U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5381–5400

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings terminated with the entry of default decrees of condemnation; (2) criminal proceedings terminated with a verdict of guilty; (3) injunction proceedings terminated with the entry of an injunction; (4) contempt proceedings for violation of an injunction which were terminated with a verdict of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation; and the criminal, injunction, and contempt proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *January 26, 1959.*

CONTENTS

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5381–5400

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

5381. Pega Palo vine. (F. D. C. No. 40311. S. No. 65–347 M.)

QUANTITY: 68 pliofilm pkgs. at Elyria, Ohio.

SHIPPED: 3–30–57, from A–1 Import Co., Chicago, Ill., by Joe C. George, Jr.

LABEL IN PART: "Pega Palo Vine Packed by A–1 Import Company Chicago, Illinois Contents: 7 grams."

RESULTS OF INVESTIGATION: Examination of the article disclosed that it was *Pega Palo vine* (*Rhynchosia pyramidalis*).

LIBELED: 6–4–57, N. Dist. Ohio.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use as an aphrodisiac, which was the purpose for which the article was intended; and 505 (a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 7–23–57. Default—destruction.

5382. Pega Palo vine. (F. D. C. No. 40312. S. No. 65–346 M.)

QUANTITY: 38 pliofilm pkgs. at Canton, Ohio.

SHIPPED: 3–30–57, from A–1 Import Co., Chicago, Ill., by Joe C. George, Jr.

LABEL IN PART: "Pega Palo Vine Packed by A–1 Import Company Chicago, Illinois."

ACCOMPANYING LABELING: Reprints entitled "Pega Palo The Vine That Makes You Virile" and streamers entitled "Pega Palo Cocktails."

RESULTS OF INVESTIGATION: Examination of the article showed it to be *Pega Palo vine* (*Rhynchosia pyramidalis*).

LIBELED: 6–7–57, N. Dist. Ohio.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use as an aphrodisiac, which was the purpose for which the article was intended; and 505 (a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 7–23–57. Default—destruction.

5383. Pego Palo vine. (F. D. C. No. 40191. S. No. 48–358 M.)

QUANTITY: 1 ctn. containing 328 cellophane bags of vine at Floral Park, N.Y., in possession of Frank Miglio.

SHIPPED: 2–19–57, from Chicago, Ill., by A–1 Import Co.

LABEL IN PART: (Bag) "Pega Palo" or "Pega Palo Vine Chicago, Illinois."

ACCOMPANYING LABELING: Reprints entitled "Pega Palo The Vine That Makes You Virile."

RESULTS OF INVESTIGATION: The reprints were printed locally for the consignee.

LIBELED: 5–3–57, E. Dist. N. Y.

CHARGE: 505 (a)—the article, when shipped, was a new drug which may not be shipped in interstate commerce since an application filed pursuant to 505 (b) was not effective with respect to the drug; and 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use for the purpose for which it was intended, namely, as an aphrodisiac.

DISPOSITION: 6–4–57. Default—destruction.

5384. Pega Palo vine. (F. D. C. No. 40212. S. No. 63–854 M.)

QUANTITY: 2 pkgs., each containing 7 pieces of vine packed separately in pliofilm envelopes, at Albuquerque, N. Mex., in possession of Robert Garcia.

SHIPPED: 4–26–57, from Chicago, Ill., by Health Enterprises.

LABEL IN PART: (Envelope) "Pega Palo Vine * * * Packed by A–1 Import Company Chicago 51, Ill. Contents: 7 grams or over."

ACCOMPANYING LABELING: Reprints entitled "The Vine That Makes You Virile."

LIBELED: 5–20–57, Dist. N. Mex.

CHARGE: 505 (a)—the article, when shipped, was a new drug which may not be shipped in interstate commerce since an application filed pursuant to 505 (b) was not effective with respect to the drug; and 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use for the purpose for which it was intended, namely, as an aphrodisiac.

DISPOSITION: 6–21–57. Default—delivered to the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5385. Peppermint tea leaves, wheat germ oil, herb laxative, concentrated broth, whole wheat, wheat germ. (F. D. C. No. 33790. S. Nos. 14–497/8 L, 14–500 L, 14–502 L, 18–317/8 L, 18–322 L.)

INDICTMENT RETURNED: 8–2–54, against El Rancho Adolphus Products, Inc., Scientific Living, Inc., and Adolphus Hohensee, all of Scranton, Pa.

SHIPPED: Between 1–21–52 and 8–14–52, from Pennsylvania to Arizona and Colorado.

LABEL IN PART: (Can) "El Rancho Adolphus Brand Genuine-Select Imported Peppermint Tea Leaves * * * Net Weight 3 Ozs. [or "Herb Laxative (Minted) * * * Net Weight 3 Oz.," "Concentrated Broth In Dry Mechanically Pulverized Form * * * Net Weight 8 Oz.," or "Improved Wheat Germ

*See also Nos. 5381–5384, 5400.

Wheat-Hearts * * * Net Weight 12 Ozs."]"; (btl.) "Adolphus Contents: One Pint Wheat Germ Oil"; (bag) "El Rancho Brand Adolphus Whole Wheat 10 Lbs. Net Weight."

CHARGE: 502 (f) (1)—the labeling of the articles failed to bear adequate directions for use, in that such labeling failed to state the purposes, conditions, and diseases for which the articles were intended, namely—

Peppermint tea leaves—to assist in the removal of gallstones; for arthritis; to rebuild the whole body; to eliminate stagnant urine and thus prevent diseases which men and women have that result from toxins produced by decomposition of stagnant urine in collapsed bladders; to contract the bladder and so force urine to drain completely; for tuberculosis; to enable the blood to utilize vitamin C; to eliminate asthma, pinworms, tapeworms, and the symptoms of worms, namely, fits, convulsions, fainting spells, gritting of the teeth while asleep, dry cough, and restlessness at night; to use as an alkalizer; to give the user health; to act as a cleanser in toxemia; for headache and rheumatism; to effect diuresis; for reducing; for colitis; for cleansing; for high blood pressure; to improve eyesight and to enable one to discard eyeglasses; for treating the eyes, muscles, blood vessels, and kidneys; for the treatment of diabetes; and for helping to cure worms, fits, convulsions, and epilepsy;

Wheat germ oil—for change of life in men and women; to reduce the frequency of heat flashes; to activate the substance which aids coagulation of the blood; for difficulty with urination; for pelvic pains and cramps, prostate gland trouble, loss of sexual fluid, sterility, and absence of pep and life; to prevent atrophy of men's glands and loss of ambition; to affect in an essential way the muscles and the valves that control the various fluids; to exert an important effect on one's entire makeup; to enable the heart to maintain a normal rhythm and the brain to perform great feats; to prevent deterioration of women's glands, resulting in loss of charm, pep, broad smiles, and winning personality; to prevent senility, weakening of the memory, inactivation of thinking, imperfect coordination between brain and muscle, and death before anything worthwhile to be recorded in history had been accomplished; to preserve life with the plenitude of its physical and intellectual manifestations and to put off death to the very last limit; to cause one to be full of vigor, buoyant, and healthy; to promote general well-being, vigor of personality, glands, and mental and physical vigor; to prevent miscarriage; to fill an essential need of nerve and muscle tissue; to treat Lou Gehrig's disease; to reduce the period necessary to replace lost spermatozoa; to act as an antisterility guard; to effect maximum growth; for reducing; to treat diabetes; for multiple sclerosis; to dissolve incrustations that create arthritis; to supply a need of the pancreas; to rebuild the body; for the heart; to keep bladder muscles firm; to prevent prolapsing of the bladder which causes retention of urine which decomposes and throws into the blood stream toxins that produce the other diseases that men and women have; and for lumbago, soreness of muscles in the back, tuberculosis, impaired hearing, and paralysis;

Herb laxative—to rid one of gallstones; to eliminate pinworms and tapeworms; and for fits, convulsions, and fainting spells;

Concentrated broth—for cleansing the system; for eliminating worms; for curing epilepsy; for helping to cure fits, convulsions, and heart trouble; for preventing blindness; for helping to reduce excess weight; and for dissolving protruding veins;

Whole wheat—for preventing idiocy; for the treatment of cancers and ulcers; for helping to cure worms, fits, convulsions, and epilepsy; and for preventing mental instability, bad temper, heart disease, eye diseases, and sex crimes;

Wheat germ—for improving eyesight and enabling one to discard eyeglasses; for promoting willpower and mentality; for helping the "personality glands"; for treating multiple sclerosis; for aiding the endocrine glands; for lowering the blood pressure; and for preventing mental instability, bad temper, heart disease, eye diseases, and sex crimes.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 11–29–54; and, on 1–6–55, the trial was concluded with the return by the jury of a verdict of guilty. On 1–7–55, the defendants filed motions in arrest of judgment and for a new trial; and, on 4–19–56, the court handed down the following opinion (140 F. Supp. 645):

WATSON, *District Judge:* "The defendants found guilty by verdict of a jury on seven counts [1] of misbranding of drugs in interstate commerce, 21 U. S. C. A. 331 (b), move for arrest of judgment [2] or for a new trial.[3]

"The trial covered a period of seventeen days and presents a transcript of one thousand two hundred eighteen pages.

"The defendants contend that the indictment fails to state facts sufficient to constitute an offense against the United States. The indictment charges the defendants with causing the introduction or delivery for introduction into interstate commerce of a number of shipments of drugs which were misbranded, in the language of 21 U. S. C. A. 352 (f) (1),[4] by reason of the failure of their labeling to bear adequate directions for use. An indictment charging the elements of the offense is sufficient. United States v. Dobrow, 346 U. S. 374. The indictment further specifies that the directions for use were inadequate because they did not state the diseases, purposes, or conditions for which the drugs were intended to be used. In order that directions for use be adequate, a statement of the intended uses must be included. Alberty Food Products, et al. v. United States, 194 F. 2d 463. The reason for this requirement is clear. It enables a layman to attempt intelligently and safely self medication. It is not sufficient that the labeling contain a minimum of information and the use of the drug be induced by collateral representations either oral or written. Adequate labeling is best suited to obtain the beneficient purposes contemplated by the Federal Food, Drug and Cosmetic Act. viz: broad protection of the consumer from misbranded drugs, and as a practical matter places no onus on those motivated by an honest belief that the claims made for their drug will be accomplished by its use. Since the government in the indictment substantially states the elements of the crime charged, it has charged an offense against the United States.

"The defendants also contend that this Court is without jurisdiction of the offense charged. The offense was committed within the Middle District of Pennsylvania. The offense did not take place where the lectures were given or the literature was distributed by the defendant Hohensee, as defendants contend, but where the drugs were introduced in interstate commerce, which was within the Middle District of Pennsylvania. The tenor of the lectures and the excerpts from the literature were offered into evidence to show that the products in question were drugs and to show their intended uses. There was substantial evidence from which the jury could find beyond a reasonable doubt that the articles were intended to be used as drugs when they were introduced into interstate commerce. This Court did have jurisdiction.

"Defendants' motion in arrest of judgment must be denied.

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[1] The Government withdrew the charges contained in counts 8 and 9 of the indictment.
[2] Rule 34, Arrest of Judgment, 18 U. S. C. A.
[3] Rule 33. New Trial, 18 U. S. C. A.
[4] § 352. Misbranded Drugs . . .
A drug . . . shall be deemed to be misbranded— . . . (f) unless its labeling bears (1) adequate directions for use; . . .

"Defendants argue that the verdict was contrary to law and the weight of the evidence. In considering the sufficiency of the evidence to sustain the verdict of the jury, this Court must take that view of the evidence which is most favorable to the government and must give to the government the benefit of all the inferences which reasonably may be drawn from the evidence. United States v. Toner, 77 F. Supp. 908. The verdict of the jury must be sustained if there is substantial evidence to support it.

"A perusal of the record in the light of these principles satisfies the Court that the verdict of the jury must be upheld. It is not necessary to recount the evidence at this time. It is sufficient to say that there was ample substantial testimony supporting no other reasonable hypothesis but that of guilt of the defendants.

"Unless there was some error in the conduct of the trial the verdict of the jury must stand. The first error assigned by the defendants is that the Court failed to rule on and to grant defendants' motion for a bill of particulars. Defendants' motion for a bill of particulars was answered when Government's counsel supplied the requested particulars.[5] No objection was made at the time as to the sufficiency of the information given nor was any objection made at any later time until a motion for a new trial was filed.

"Moreover, the indictment in each count refers to specific shipments of the products on designated dates to designated destinations. Thus, the information contained in the indictment and the information given defendants in response to their request for a bill of particulars enabled them to prepare their defense, the traditional purpose for which a bill of particulars is allowed. Norris v. United States, 152 F. 2d 808.

"The next reason advanced by the defendants in support of their motion for a new trial is that the Court erred in granting the Government additional peremptory challenges even though counsel for the defendants stipulated that the government should have additional challenges. The defendants argue that this stipulation was entered into without the presence of the defendant, Hohensee.

"In spite of the cases cited by defendants to the broad effect that a defendant must be present at all proceedings after an indictment is returned, later cases hold that the right is not so sweeping. It is apparent that in every bench conference between Court and counsel, the defendant has no voice, and in effect is not present even though rulings may be made which vitally affect him. In the Third Circuit, perhaps the leading case on the subject is United States v. Johnson, 129 F. 2d 954 (C. A. 3, 1942), where the Court made an exhaustive analysis of precedent to determine the propriety of the exclusion of defendant for a portion of the proceedings, in that case during argument on a point of law.

"There are occasions during the proceedings after an indictment is returned when it is not necessary that the defendant be present. Johnson v. United States, 318 U. S. 189, and a conference at which the number of peremptory challenges is agreed upon by stipulation is one of those occasions. A defendant in a criminal case is bound by the stipulation of his counsel, and his specific assent is needed only as to waiver of his constitutional or other 'substantial' legal rights. Himmelfarb v. United States, 175 F. 2d 924 (C. A. 9, 1949). It has repeatedly been held that the peremptory challenges are governed by statute and not by the Constitution. United States v. Macke, 159 F. 2d 673 (C. A. 2, 1947).

"The defendants also contend that the Court erred in permitting counsel from the Food and Drug Administration to take part in the conduct of the case.

"Defendants argue that Mr. Risteau of the Department of Health, Education, and Welfare was improperly permitted to take part in the trial of the case, even though during the trial, documents were submitted showing his appointment as a special assistant to the United States Attorney. A similar factual situation was held not to constitute error, William v. United States, 218 F. 2d 276 (C. A. 4, 1954).

"The defendants also contend that the order of closing argument was improper.

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[5] See Transcript, pages 42–44, inclusive.

"Defendants cite a number of state cases to the effect that their counsel should have been entitled to present their closing argument after at least a portion of the argument of Government counsel. The practice in this District is for the complaining party to present its entire closing argument after argument of the defendant, unless the defendant presents no evidence, in which case the defendant argues last. Since defendants here presented evidence, they can make no complaint. In fact there was no complaint until the filing of their amended motion for new trial. It would seem apparent that, in the absence of any request for rebuttal at the trial, defendants have no standing to complain at this time. Furthermore, the order of argument is entirely within the Court's discretion. Hardie v. United States, 22 F. 2d 803, cert. denied 276 U. S. 636.

"The defendants also contend that the Court erred in submitting a copy of the indictment to the jury which copy did not include the portions relating to the prior conviction of the Defendant Hohensee.

"Defendants argue that the allegations of the previous conviction of the Defendant Hohensee in the indictment were improper, in that the prior conviction was a matter only to be considered by the Court in imposing sentence, and that it was error to submit the indictment to the jury without the portions relating to the prior conviction. At the trial counsel argued that cases under the Prohibition Act of the 1920's were not applicable in the present situation because of a specific provision in that law for the pleading and proof of prior convictions.

"The practice of alleging and proving prior convictions in order to permit the imposition of an increased penalty has been followed under a variety of statutes. The case most directly in point is United States v. Berkowitz, 45 F. Supp. 564 (W. D. Mo., 1942), a case under the Fair Labor Standards Act of 1938, where the court cited exhaustive authority for the proposition that a prior conviction must be both alleged and proved. In that case, as in the present one, the contention was made that the proper method of handling the problem was to permit the first conviction to be brought to the attention of the court in an informal manner, and it was this argument that the court rejected in its ruling.

"With respect to the omission of the allegations of prior conviction from the indictment sent to the jury, such allegations were alleged and proved until the Court of Appeals for the Second Circuit held in United States v. Modern Reed and Rattan Co., Inc., 159 F. 2d 656 (C. A. 2, 1947), cert. den. 331 U. S. 831), that it was error to bring to the attention of the jury a prior conviction. While there are no reported decisions on the point, it would seem that there could be no possible prejudice to a defendant in keeping from the jury the fact of the prior conviction until after the return of a verdict on the instant trial. See Rule 52 (a), Rules of Criminal Procedure.

"The defendants also argue that the Court made several errors in ruling on evidence.

"Defendants' objections to the evidence are based upon a number of general grounds.

"The first of these relates to the admissibility of the testimony of the witnesses Barnes, Eichenauer, and Megaarden as to their conversations with the Defendant Hohensee when making arrangements for the shipment of the El Rancho Adolphus products to the store of Barnes and Eichenauer. Since these conversations were for the very purpose of arranging for the goods to be shipped, they could not have taken place after the shipment as stated by defendants.

"Hohensee's conversations with these witnesses were relevant to show his connection with the shipment of the misbranded drugs from Scranton to Phoenix and Denver. Other evidence, including bank records, the stipulation as to Hohensee's Presidency of Scientific Living, Inc., and his common address with the corporations all show his relationship with those corporate defendants.

"Still other evidence, including the transportation records and labels on the containers of the drugs, were presented to tie in the corporations with the violative shipments. Cf. Strong, Cobb & Co., Inc. v. United States, 103 F. 2d 671 (C. A. 6, 1939). This evidence is all independent of any conversation which Hohensee may have had with any of the witnesses in question.

"The Government showed that the content of the lectures was proved to estab-

lish the uses for which the articles were intended from the time of shipment until they were disposed of to the public.

"Defendants also argue that the samples supplied by the witnesses Barnes and Eichenauer to food and drug inspectors were obtained in violation of Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 374) which, when the samples were picked up in 1952, had not been amended to its present form.

"The former Section 704 conferred upon the inspectors of the Food and Drug Administration the power to enter, after obtaining permission of the owner, operator, or custodian of any 'establishment' where 'drugs' were 'held' after their introduction into interstate commerce, and to make inspections necessary for the enforcement of the Act. This right to make inspections has been held, in conjunction with Section 702 (b), 21 U. S. C. 372 (b), to include the right to obtain samples. United States v. 75 cases * * * Peanut Butter, 146 F. 2d 124 (C. A. 4, 1944) cert. den. 325 U. S. 856.

"In the present case it is undisputed that Barnes and Eichenauer willingly gave the inspectors permission to inspect and to take samples. Defendants argue, however, that a sample taken according to the above statutory procedure can only be used in evidence against the person in whose establishment it is found and who gave permission. They further contend that its use against any other person is in violation of the Fourth Amendment. It is well-established, however, that a person cannot complain under the Fourth Amendment when a third person consents to a search of property belonging to the defendant but in the possession of the third person. United States v. Walker, 197 F. 2d 287 (C. A. 2, 1954). In the present case, the property sampled by the inspectors did not even belong to defendants.

"It is apparent that if any other view were adopted, it would be virtually impossible to bring a criminal action under the Act. For Section 331 (a), 21 U. S. C., makes it a violation of the Act to introduce or deliver for introduction into interstate commerce a drug that is misbranded. Since the Government must prove the existence of the violative article by sampling, and since the article will never, after its introduction into interstate commerce, be in possession of the one who has introduced it, the shipper would never be on hand to give permission to sample an article. Section 704, even before amendment, was clear enough in authorizing sampling at destination with permission obtained from the person then in possession. Here the inspectors obtained permission from the owner, operator, or custodian of the premises where the samples were obtained. As pointed out above, their action was in no way improper.

"The defendants next contend that the Court erred in instructing the jury that intent is not an element of the offenses charged.

"It is well established that it is not necessary to allege or prove guilty knowledge or intent in cases brought under the Federal Food, Drug, and Cosmetic Act. In the leading cases on this point, United States v. Dotterweich, 320 U. S. 277, 285–286, the Supreme Court stated:

> * * * Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless. *United States* v. *Kaadt*, 171 F. 2d 600 (C. A. 7).

"Defendants now argue that because the offenses here charged to the defendant Hohensee are felonies, the present case is distinguishable from those cited above, which involved misdemeanors. This is not a valid distinction for in a number of cases the Supreme Court has held that other factors determine whether intent is an element of the offense. Thus, in Morisette v. United States, 342 U. S. 246, which contains an extensive discussion and analysis of intent in both 'common law' crimes and offenses which were unknown under the common law, the Court stated, at page 259:

> It was not until recently that the Court took occasion more explicitly to relate abandonment of the ingredient of intent, not merely with considerations of expediency in obtaining convictions, nor with the malum

> prohibitum classification of the crime, *but with the peculiar nature and quality of the offense.* We referred to ". . . a now familiar type of legislation whereby penalties serve as effective means of regulation," and continued, "such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger." But we warned: "Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting." *United States* v. *Dotterweich*, 320 U. S. 277, 280–281, 284. [Emphasis added.]

In other cases, including United States v. Balint, 258 U. S. 250, the United States v. Behrman, 258 U. S. 280, convictions of felonies were upheld even though no criminal intent was alleged or proved.

"Defendants next argue that they were deprived of a fair trial by Government counsel's summation, principally with reference to statements that the defendant Hohensee 'schemed' to violate the law. They further argue that there was no evidence to support such statements.

"This contention is not borne out by the record, which shows almost without contradiction that Hohensee represented his products for a variety of serious diseases and conditions in his lectures and booklets and that the labeling of the products did not say anything about these diseases and conditions. In referring to this method of merchandising as a 'scheme' to avoid the law, counsel was only paraphrasing the language of United States v. Alberty Food Products, 194 F. 2d 463 (C. A. 9, 1952) where the court stated with respect to the requirement that the labeling of a drug should state the purposes and conditions for which it was intended:

> Adequate labeling is best suited to obtaining the beneficient purposes contemplated by the Act, viz: broad protection of the consumer from adulterated or misbranded drugs, etc., *and as a practical matter places no burden on those motivated by an honest belief that the claims made for the drug will be accomplished by its use.* [Emphasis added.]

"Other evidence shows that Hohensee was indeed attempting to avoid the provisions of the law. Mrs. Barnes testified that Hohensee took the invoice and shipping records for his products from her because the Food and Drug Administration could not maintain any action against him without records of interstate shipment.

"It is also apparent from the record that Hohensee was being less than candid when he would state in one breath that he did not diagnose or prescribe for disease, and then in the very next proceed to diagnose a serious disease and recommend one of his 'diets' for its treatment. The testimony of Mr. Kimlel and Miss Streessner is full of instances of this type of evasive conduct, and defendants' evidence, in particular the testimony of Mrs. Anderson, corroborates that of the Government.

"These facts in themselves form a sufficient basis from which it could be inferred that the defendant Hohensee knew that he was violating the law and that he was taking whatever steps he could to forestall prosecution. Argument based upon the evidence and inferences from the evidence is always proper. Eastman v. United States, 153 F. 2d 80 (C. A. 8, 1946), cert. den. 328 U. S. 352.

"However, even if there was no evidence in the record to support the statement with respect to Hohensee's purpose to violate the law, the Court on two occasions, first in its general charge, and again when defendants first objected to Mr. Teller's remarks, instructed the jury to disregard all comments of counsel and to decide the case on the evidence. Czarnecki v. United States, 95 F. 2d 32 (C. A. 3, 1938); Chadwick v. United States, 117 F. 2d 902 (C. A. 5, 1951) cert. den. 313 U. S. 585. It is only rarely that the court should interrupt argument of counsel in the absence of objection, and, as pointed out above, the record provides ample basis for the arguments.

"Defendants' next argument is that the jury failed to consider all of the evidence, and was unduly influenced by allegedly improper argument of Gov-

ernment counsel. They also request the Court to grant permission to take testimony of jurors for the purpose of determining what effect these allegedly erroneous statements may have had upon them.

"Mattox v. United States, 146 U. S. 140, is cited by defendants for the proposition that jurors may be interrogated for the purpose of determining when an improper influence has been exerted on them. Actually the case holds that the jury may be questioned as to whether they saw a newspaper account published while they were deliberating, but the case specifically denies counsel the right to question jurors as to the effect which the newspaper account had on their minds.

"The rule in the *Mattox* case was recently and forcefully stated by Chief Judge Gourley of the Western District of Pennsylvania in United States v. Nystrom, 116 F. Supp, 771, 777 (1953) :

> I am compelled to unequivocally disapprove the practice of interviewing a juror after a trial as to his state of mind during the trial. ' United States ex rel Daverse v. Hohn, 3 Cir., 198 F. 2d 934.

"The remaining reasons assigned by defendants in support of their motions are entirely without merit and require no discussion.

"It is the conclusion of this Court that the record shows no error in the trial that was prejudicial to the defendants. The verdicts were not contrary to the law. Defendants received a fair trial and the verdicts were supported by substantial evidence. Defendants' motion in arrest of judgment will be denied. Defendants have failed to advance any valid reason why a new trial should be granted and defendants' motion for a new trial will be denied.

"An appropriate order will be filed herewith."

Pursuant to the above opinion, the court, on 4–19–56, ordered that the defendants' motions in arrest of judgment and for a new trial be denied. On 5–25–56, the court fined El Rancho Adolphus Products, Inc., $700 and Scientific Living, Inc., $700 and sentenced Adolphus Hohensee to imprisonment for 1 year and 1 day. An appeal was taken to the United States Court of Appeals for the 3d Circuit; and, on 1–29–57, the following opinion was handed down by that court (243 F. 2d 367) :

McLaughlin, *Circuit Judge:* "Appellants were indicted on nine counts for causing the introduction and delivery for introduction into interstate commerce of misbranded drugs, contrary to the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. 321 et seq.[1] Counts VIII and IX were withdrawn by

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[1] 21 U. S. C. Chap. 9, Sub. Chap. II, Sec. 321 (g), (k), (m) :
"For the purposes of this Chapter

* * * *

"(g) The term 'drug' means * * * (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals ;

* * * *

"(k) The term 'label' means a display of written, printed, or graphic matter upon the immediate container of any article ;

* * * *

"(m) The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

21 U. S. C. Chap. 9, Sub. Chap. III, Sec. 331 (a) :
"The following acts and the causing thereof are hereby prohibited :
"The introduction or delivery for introduction into interstate commerce of any * * * drug * * * that is * * * misbranded.

21 U. S. C. Chap. 9, Sub. Chap. III, Sec. 333 (a) :
"Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to or both such imprisonment and fine ; but if the violation is committed after imprisonment for not more than one year, or a fine of not more than $1,000 a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine."

21 U. S. C. Chap. 9, Sub. Chap. V, Sec. 352 (f) :
"A drug * * * shall be deemed to be misbranded—

* * * *

"Unless its labeling bears (1) adequate directions for use."

the government in the course of the trial and nolle prossed. All three appellants were convicted on the remaining seven counts.

"The government's theory and proof involved two parallel sets of incidents. The individual appellant is president of one of the corporate appellants, Scientific Living, Inc. and the moving spirit in both. Counts I, II and III of the indictment concern Hohensee going to a food store in Phoenix, Arizona, advising the proprietor that he intended lecturing on health subjects in Phoenix shortly and seeking his cooperation. Appellant gave the storekeeper leaflets and advertising copy to be distributed and used for arousing interest in the lectures.[2] He provided for stocking El Rancho Adolphus brand products in the health food store. Demand for these products was to be created by the forthcoming lecture series.

"Shipments of El Rancho Adolphus products began arriving at the Phoenix store in the latter part of January 1952 and were invoiced from one or the other of the corporate appellants at Scranton, Pennsylvania. The lectures were given by appellant at Phoenix from February 11 to March 6, 1952. At these lectures printed materials were distributed dealing with most chronic diseases and physical complaints, suggesting diets which included large quantities of El Rancho Adolphus products as remedies. According to the testimony, the oral representations of appellant at the lectures, regarding the subject matter of Count I, were astounding; peppermint tea, for example, was recommended for gall stones, colic, flatulence, headache, rheumatism, high blood pressure, arthritis, prostate trouble, lumbago, fits, convulsions, colitis, tuberculosis, asthma, pin worms and tape worms. The label on the El Rancho Adolphus brand peppermint tea leaves had only the following directions: 'Used as a delicious refreshing table beverage. Take one level teaspoon of Adolphus peppermint for each cup of water, steep for four minutes. Do not boil. Sweeten to taste.'

"Counts II and III arise out of other products of the Phoenix promotion, namely, wheat germ oil and herb laxative. There were similar fantastic representations of their curative qualities.

"Counts IV, V, VI and VII cover the campaign in Denver where Hohensee lectured during the months of July through September 1952. The preliminary arrangements for that city were made by one Miguarder, a government witness at the trial. The local retail outlet for the El Rancho Adolphus products was Leeds Health House, operated by Mrs. Ethel Barnes, who also testified for the government. El Rancho Adolphus brands of concentrated broth, whole wheat, peppermint tea leaves, and wheat germ called by the trade name, 'Wheat Hearts,' are the products alleged in those counts to have been misrepresented.

"Appellants attack the constitutionality of 21 U. S. C. Section 352 (f) (1) on the ground that the statutory language 'Bears adequate directions for use' with reference to misbranding is too vague, indefinite and uncertain if con-

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21 U. S. C. Chap. 9, Sub. Chap. VII, Sec. 371 (a):
"The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary." Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act. Sec. 1.106, 21 CFR 1.106:
"Drugs and Devices: directions for use—

> "(a) Adequate directions for use. 'Adequate directions for use' means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:
> "(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising * * *."

[2] The leaflets described the lectures as including "* * * hope-awakening new light on scores of specific conditions which today are the scourge of mankind. What does science say about Cancer? Diabetes? Rheumatism? Liver disorders? Chronic constipation? Colitis? Stomach ulcers? Kidney stones? Kidney disease? Morning mouth? Tooth decay? Bleeding gums? Tuberculosis? Sinusitis? Asthma? Common Cold? Irritability? Vague pains? Scurvy? Rickets? Beri Beri? Glaucoma? Neuritis? Cataracts? Sexual Impotency? Frigidity in Women? Neurotic Symptoms? Heart disease? High blood pressure? Low blood pressure? Rebuilding of blood? Anemia? Arteriosclerosis? Hemorrhoids? Insomnia? Fatigue? Foot trouble? Better eyes without glasses? How to conquer premature old age? Better eyes without glasses! A startling revelation by a man who was actually blind! Today he enjoys perfect vision." The newspaper advertisements were similar in context.

strued to proscribe their activities. In Kordel v. United States, 335 U. S. 345 (1948) the Supreme Court upheld a conviction where the circumstances were very close to the case at bar. That decision definitely disposes of any question of constitutionality here.

"In Kordel promotional materials were shipped separately for the products intended for use as drugs.[3] The Supreme Court reaffirmed its position as outlined in United States v. Dotterweich, 320 U. S. 277 (1943) and United States v. Sullivan, 332 U. S. 689 (1948) that this legislation be given a liberal interpretation to effectuate its high purpose of protecting unwary consumers in vital matters of health. The intended uses of the products in the present issue as in Kordel to cure, ameliorate or prevent diseases. The evidence to prove their uses included both graphic materials distributed and testimony of oral representations to users and prospective users. The latter are no less relevant on the question than the former. Both show that the products shipped were to be used as drugs. Alberty Food Products v. United States, 194 F. 2d 463 (9 Cir. 1952). The crime is that the labels on the containers were insufficient for the purposes for which the products were to be used. The statute prohibits the shipment of any products that are to be used as drugs, and are inadequately labeled for that purpose.

"Appellants challenge the sufficiency of the evidence to support the verdict. Their main thrust is against the time sequence of the various events in both Phoenix and Denver where the evidence of misbranding is primarily the oral representations and printed material distributed at the lectures. It is argued that since the lectures occurred some weeks after the products were introduced into interstate commerce, there was no proof of a medicinal or curative purpose or use of the products at the time of the shipments from Scranton to Phoenix and Denver. That problem was decided in Kordel, supra. There, the food products, including vitamins, minerals and herbs, were labeled innocuously as health foods. The advertising materials which proved the products were drugs for the amelioration of various ills were shipped separately both before and after the products.[4] The Supreme Court specifically held that:

> The false and misleading literature in the present case was designed for use in the distribution and sale of the drug, and it was so used. The fact that it went in a different mail was wholly irrelevant whether we judge the transaction by purpose or result. And to say that the prior or subsequent shipment of the literature disproves that it "is" misbranded when introduced into commerce within the meaning of § 301 (a), is to overlook the integrated nature of the transactions established in this case.
>
> Moreover, the fact that some of the booklets carried a selling price is immaterial on the facts shown here. As stated by the Court of Appeals, the booklets and drugs were nonetheless interdependent; they were parts of an integrated distribution program. The Act cannot be circumvented by the easy device of a "sale" of the advertising matter where the advertising performs the function of labeling.

"Appellants further contend that false advertising is exclusively within the jurisdiction of the Federal Trade Commission. That argument was rejected in Kordel.

"Hohensee insists the principle that intent is not an element of the offenses charged[5] should not have been applied to him since as a second offender, if convicted, he would be subject to felony penalties. His guilt falls into the felony category not because of evil intent but because of the maximum sentence of three years for second offenders provided by Section 333 (a) of 21 U. S. C. The Act imposes criminal sanctions as a means of regulating activities so dangerous to the public welfare as not to permit of exception for good faith

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[3] United States v. Cruez, 144 F. Supp. 229 (D. C. E. D. Ill. 1956) involves a conviction based solely on evidence of oral representations. Weeks v. United States, 245 U. S. 618 (1918), affirmed a food misbranding conviction based on oral representations.

[4] The dissent points out "The evidence under one count was that the drugs were shipped July 10, 1942, while the booklets * * * were sent a year and a half later, January 18, 1944."

[5] See Morisette v. United States, 342 U. S. 246 (1952) for an exhaustive discussion of the principle.

or ignorance. A person acts at his peril in this field. United States v. Dotterweich, supra. The instant facts are well within the rule established by United States v. Balint, 258 U. S. 250 (1922) which sustained a maximum sentence of five years under another no intent statute, the Narcotic Act of 1914, 38 Stat. 785. And see United States v. Behrman, 258 U. S. 280 (1922).

"Hohensee had been convicted previously under the Federal Food, Drug and Cosmetic Act and that was pleaded in the indictment in order to call forth the second offender penalties under Section 303 (a) of 21 U. S. C. Knowledge of the prior conviction was meticulously kept from the jury and reference to it was blocked out of the copy of the indictment which went to the jury room. We find that no prejudice to the accused resulted from the procedure followed.

"Appellants suggest they were seriously harmed when, a week prior to the start of the trial, in the presence of the jury panel, Hohensee, explaining that his attorney was ill, was arguing pro se for a bill of particulars and the judge commented 'I don't think you need a lawyer.' The record does not reveal any prejudicial connotation. Presumably it was an offhand complimentary pleasantry coupled with an indication that the court would protect his interests. In any event the transcript shows three of the defense attorneys in court at the time with two of them seemingly discussing the information desired.

"Appellants also complain of a remark (lifted out of a sentence) the judge made at a sidebar conference during the trial. A Food and Drug inspector was on the witness stand. She testified she had attended three of Hohensee's Denver lectures. *Prior to any testimony of what Hohensee had said*, appellants, with the court's permission, objected to all such testimony as 'incompetent, irrelevant and immaterial to prove the allegations of the indictment, and, furthermore, oral statements cannot constitute misbranding of an article.' According to the transcript the court then stated at this sidebar colloquy with counsel, 'If I uphold your objection we would dismiss this jury, but I cannot do it with all the preparation in this case. Why this man must be a terrible person; I do not know, but anyway I am not going to form any opinion at all. It is none of my business, so you just go ahead and I will overrule you.'

"On occasion, stream of thought language, wrenched away from its setting, may not seem too clear later but that difficulty is not present in the above quoted statement. Manifestly the judge, feeling that the first part of his offhand observation did not properly express his state of mind, remedied it immediately and in the same sentence. No motion was made at the time or thereafter concerning it. The only purpose of counsel coming to the side of the bench was to prevent the jury overhearing the motion. There is no evidence that purpose failed.

"A third objection is voiced to the court's expressions with reference to the cost of the trial. In denying the motions for acquittal, the court did allude to the large trial expense but in its next sentence and the same paragraph stated 'If I determine that I am in error about this (the denial of the motions) at any time I shall gladly grant a new trial, or even enter a judgment of acquittal, if I think I should * * *.' Of the two other allusions to trial cost in appellants' appendix, one has to do with the court trying to narrow the trial scope. In the other, the court, at considerable length, rejected the government's plea not to postpone the trial at the defense request. The government urged it had expended large sums of money in preparation. The court concluded its decision to allow the continuance by saying:

> Now, this all means that the preservation of freedom is very expensive, just like everything else, more so every day, and it always has been. So I am not going to sustain the objections to the motion because of the expense, and I will grant the motion for a continuance, and I will fix November 29, 1954 at 2 o'clock in the afternoon for the trial of this case.

"Appellants assert the district attorney prevented a fair trial to them by asking leading questions. The one illustration of these in appellants' appendix shows their objection to the particular question was sustained without argument. As to several remarks of the district attorney, now protested, appellants have not bothered to set out the record of these in their appendix. Those that are shown do not evidence substantial harm, individually or collectively.

"Appellants before us assail the government summation but made no objection to it during its progress or after it had been concluded; examining it we do not find that it substantially exceeded fair inferences from the evidence. Its final note stressed that the government's concern was '* * * *with the misbranding of these drugs and we want them properly labeled.*' [Emphasis supplied.] As he finished his summation government counsel said to the jury, 'All I ask you is that you render a fair and proper verdict in this case * * *.' In the thorough and scrupulously fair charge, among many other things, the court said:

> In considering the evidence before you your attention is directed to the fact that not all matters coming to your attention in this trial can be considered by you as evidence. The indictment, the opening remarks of counsel, the arguments of counsel, the remarks of counsel, and the remarks of the Court during the trial of the case are not evidence and are not to be considered by you as such in determining the facts of the case.

"We have examined all other points of appellants. They do not raise substantial questions and need not be discussed at length."

"The judgments of the district court will be affirmed."

A petition for a rehearing was filed by the defendants with the court of appeals; and, on 3–1–57, the court denied the petition in the following opinion:

PER CURIAM: "The petition for rehearing contains nothing of merit which has not been heretofore presented to and considered by this court.

"There is a copy of an affidavit, executed February 11, 1957, annexed to the petition. It is submitted by appellants as an example of other affidavits which they state they are prepared to produce. It characterizes language, tone, range of voice and manner of the trial judge on two occasions; the first, during a pre trial motion and the second, during the course of the trial. Both those incidents were argued fully and disposed of specifically by our opinion in the case. The material offered was never before the trial court. It is entirely outside the record. In those circumstances the deliberate attempt to bring it before this court is inexcusable.

"The petition for rehearing will be denied."

A petition for a writ of certiorari was filed with the United States Supreme Court, and was denied on May 27, 1957.

5386. **Appetum.** (F. D. C. No. 40180. S. No. 59–375 M.)

QUANTITY: 6 ctns., 10,000 tablets each, at Philadelphia, Pa., in possession of Philadelphia Ampoule Laboratories.

SHIPPED: 5–29–56, from Brooklyn, N. Y., by Sweets Laboratories, Inc.

LABEL IN PART: (Ctn.) "Ford Gum & Machine Co., Akron, N. Y. Sweets Labs, Inc., Brooklyn, N. Y."

RESULTS OF INVESTIGATION: The dealer stated that it was his intention to repackage the material in bottles holding 28 tablets and relabel as follows: "28 Tablets appetum high potency Vitamin B_1 – B_{12} * * * Increases appetite and stimulates growth * * * speeds convalescence. Assists in the treatment of chronic diarrhea and celiac diseases * * * Ingredients Vitamin B_1 . . . 10 mg. * * * Vitamin B_{12} . . . 25 mcg."

Analysis showed that the article contained less than 5 mg. of vitamin B_1 per tablet.

LIBELED: 4–26–57, E. Dist. Pa.

CHARGE: 502 (f) (1)—the article, when shipped and while held for sale, failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: 5–27–57. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

5387. Digitoxin powder. (F. D. C. No. 40334. S. No. 62–192 M.)

QUANTITY: 1 100-gram btl. at New York, N. Y.

SHIPPED: 1–15–57, from Paris, France, by Expandia.

LABEL IN PART: "Digitoxin U. S. P."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 54.1 percent of digitoxin.

LIBELED: 7–5–57, S. Dist. N. Y.

CHARGE: 501 (b)—the strength of the article, when shipped, differed from the standard for digitoxin set forth in the United States Pharmacopeia since the article contained less than 90 percent of digitoxin, the minimum permitted by the standard.

DISPOSITION: 10–17–57. Default—destruction.

5388. Digitoxin powder. (F. D. C. No. 39889. S. No. 59–018 M.)

QUANTITY: One ctn. containing 100 grams at Philadelphia, Pa.

SHIPPED: 1–28–57, from New York, N. Y., by Desmo Chemical Corp.

LABEL IN PART: "Net 100 gms. * * * Digitoxin U. S. P. * * * Assay: Digitoxin 99.1 percent Loss on drying: 0.62 percent."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 79 percent of digitoxin.

LIBELED: 3–19–57, E. Dist. Pa.

CHARGE: 501 (b)—the strength of the article, when shipped, differed from the standard for digitoxin set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin, the minimum permitted by the standard.

DISPOSITION: 8–28–57. Default—destruction.

5389. Vitamin capsules. (F. D. C. No. 40198. S. No. 62–186 M.)

QUANTITY: 162 100-capsule btls. at Bronx, N. Y.

SHIPPED: 1–8–57, from Newark, N. J.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the declared amount of vitamin B_{12}.

LIBELED: 5–29–57, S. Dist. N. Y.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it was represented to possess, namely, 10 micrograms of vitamin B_{12}; and 502 (a)—the label statement "Vitamin B–12 10 Mcgms." was false and misleading.

DISPOSITION: 7–16–57. Default—destruction.

5390. Halazone tablets. (F. D. C. No. 40318. S. No. 67–482 M.)

QUANTITY: 25 cases, containing 2,575 btls., at Falls Church, Va.

SHIPPED: Prior to 10–7–55, from North Chicago, Ill.

LABEL IN PART: (Btl.) "100 Water Purification Tablets for Purifying Drinking Water in Canteens Halazone N. N. R. * * * Each tablet contains: 0.004 Gm. (1/16 grain) of Halazone with sodium carbonate, sodium chloride and boric acid."

RESULTS OF INVESTIGATION: Examination showed that the article contained from 35 to 68 percent of the labeled amount of halazone.

LIBELED: 6–12–57, E. Dist. Va.

CHARGE: 501 (b)—the strength of the article, while held for sale, differed from the standard for halazone tablets set forth in the National Formulary.

DISPOSITION: 1–14–58. Default—destruction.

5391. Orgone Energy Accumulators. (Inj. No. 261.)

COMPLAINT FOR INJUNCTION FILED: 2–10–54, Dist. Maine, against Wilhelm Reich Foundation, a corporation, Rangeley, Maine, Wilhelm Reich, an individual, and Ilse Ollendorff, also known as Mrs. Wilhelm Reich, to enjoin the defendants (1) against causing the introduction and delivery for introduction into interstate commerce of devices known as *Orgone Energy Accumulators* and adulterated and misbranded as described below and (2) against causing such devices to be adulterated and misbranded while held for sale after shipment in interstate commerce.

NATURE OF DEVICE: The complaint alleged that the *Orgone Energy Accumulator* devices were available in several styles and models, such as:

(1) The *box-style Orgone Energy Accumulator* which was designed to stand upright and was large enough to permit an adult to sit inside. The height, width, and depth were several inches less than those of an ordinary telephone booth. The top, bottom, sides, and door were constructed with alternating layers of organic and metallic material. The outer layer was of Celotex or plywood, then alternating layers of steel wool and rock or glass wool, with the inside layer of galvanized sheet metal or plastic wire mesh. The door was hinged to one side and usually had an open window or portions cut out at the top and bottom for ventilation. There was a two-section removable seat also made in layers. A small section was cut out at a corner of the seat for the insertion of a length of B–X type cable, into the other end of which a funnel could be placed. The drop section might be used as a chestboard by placing it upright in front of the chest of the person sitting in the box; chestboards were also made and sold separately. A device with six layers was called a three-fold *Orgone Energy Accumulator;* one with two additional layers was called four-fold, and so on;

(2) The *"Shooter" type Orgone Energy Accumulator* which was a box approximately one cubic foot in size, all sides of which were made in the manner described above;

(3) The *blanket style Orgone Energy Accumulator* which was constructed of wire mesh, with several alternating layers of organic and metallic material covered on the outside with plastic. It was made in three portions which could fold down flat. It was for use in bed or local application; one section could be placed under the mattress and the other two over the patient;

(4) The *funnel style Orgone Energy Accumulator* which also was constructed of wire mesh, with several alternating layers of organic and metallic material covered with plastic.

The *Orgone Energy Accumulators* were not connected with, or plugged into, any source of electrical or other type of energy or power.

The above-described *Orgone Energy Accumulators* were offered by the defendants both for sale and for rental.

The complaint alleged also that the defendants had made the following claims with respect to orgone energy and the operation of the *Orgone Energy Accumulators;* that Defendant Wilhelm Reich had discovered a form of energy present in the atmosphere for which he coined the term "orgone energy"; that the alleged energy was life energy, had therapeutic value, and was beneficial in the cure, mitigation, treatment, and prevention of disease; that Wilhelm Reich had invented a device in 1940 which collected this alleged energy from the atmosphere and accumulated it in the device, where it was usable for scientific, educational, and medical purposes; that the organic material, which should constitute the outermost layer of the accumulator, attracted and absorbed the alleged orgone energy; that metallic material, though it attracted the energy, quickly reflected it; that by layering the accumulators with the organic material always on the outside, as above-described, a direction was thereby given to the alleged energy from the outside to the inside where the alleged energy was collected and concentrated; that the enclosure within the device constituted an alleged orgone energy field and the person in the enclosure constituted another such field; that the energy fields of the two systems would make contact; that both the person and the energy field would begin to "luminate," become excited and, making contact, drive each other to higher levels of excitation; and that the user would become aware of this alleged phenomenon through feelings of prickling, warmth, relaxation and reddening of the face, accompanied by an increase of body temperature from ½ to 1½ degrees Fahrenheit.

The complaint alleged further that the defendants stated that there was no mechanical rule as to the length of time a person should sit in the devices; that, on the average, a person required from 5 to 30 minutes daily; that, with regular use, this time could be shortened from 30-minute to 10-minute sessions; that the necessary time for the sittings was decreased in accordance with the number of layers the devices happened to have; that a patient could sit in the devices clothed or unclothed, but woolen or too heavy clothing was not recommended since such clothing prevented quick contact and lumination; and that it was better for a person to indulge in two or more short sittings rather than one protracted sitting as the latter could cause serious damage.

ACCOMPANYING LABELING: Books entitled "The Discovery of the Orgone" by Wilhelm Reich (Vol. I—"The Function of the Orgasm" and Vol. II—"The Cancer Biopathy"); "The Orgone Energy Accumulator—Its Scientific and Medical Use"; "Ether, God and Devil" by Wilhelm Reich; "Annals of the Orgone Institute"; "Listen Little Man" by Wilhelm Reich; "The Mass Psychology of Fascism" by Wilhelm Reich; "Character Analysis" by Wilhelm Reich; "International Journal of Sex-Economy and Orgone Research" (4 vols. published 1942 through 1945); "The Murder of Christ" by Wilhelm Reich; "People in Trouble" by Wilhelm Reich; "The Oranur Experiment"; Cosmic Superimposition" by Wilhelm Reich; and "The Sexual Revolution."

Booklets entitled "Orgone Energy Bulletin" (a quarterly publication); "Emotional Plague Versus Orgone Biophysics"; "Internationale Zeitschrift Fur Orgonomie"; "Orgone Energy Emergency Bulletin"; "Oranur Project"; and "Additional Information Regarding Soft Orgone Irradiation."

Miscellaneous circulars and sheets entitled "Application For Use Of The Orgone Energy Accumulator"; "How To Use The Orgone Accumulator"; "Instructions For Assembling The Orgone Accumulator"; "Catalogue Sheet"; and "Physicians Report"; "To All Users of The Orgone Energy Accumulator"; and "Instructions For The Orgone Energy Accumulator Blanket."

The complaint alleged further that the items of written, printed, and graphic matter published and distributed by the Orgone Institute Press, the publishing house of the defendant, Wilhelm Reich Foundation, consisted of books, book covers, booklets, periodicals, journals, pamphlets, bulletins, brochures, order blanks, announcements, catalogs, catalog sheets, form sheets, application forms for sale and rental of the *Orgone Energy Accumulators*, and instruction sheets.

The complaint charged that there were many ways in which prospective purchasers of the devices could learn about them. These encompassed conversations with persons acquainted with the devices, as well as advertising campaigns conducted by the defendants in newspapers, journals, and in magazines which promoted the sales of books, periodicals, booklets, journals, bulletins, and other publications of the defendants. This advertising announced the existence, availability, and prices of defendants' publications on the discovery and medical use of Orgone Energy by employing the *Orgone Energy Accumulator*. Announcements appeared on the removal covers of defendants' booklets, pamphlets, and journals. Defendants' publications were exhibited at booksellers and library association conventions and conferences, and were listed in book reference sources. Also, the defendants had made use of a mailing list of approximately 7,500 names and had printed 10,000 copies of a catalog describing the contents of each of their books and periodicals, and had mailed out approximately 7,000 copies of this catalog.

CHARGE: 501 (c)—the strength of the devices differed from, and their quality fell below, that which they purported and were represented to possess in that they were not capable of collecting from the atmosphere and accumulating in said devices the alleged Orgone Energy.

502 (a)—the labeling accompanying the devices, when shipped and while held for sale, was false and misleading as follows:

(1) The mimeographed sheet entitled "How To Use The Orgone Accumulator * * * Please Read Carefully" represented and suggested that the devices be kept at least three rooms away from an operating X-ray machine; that the devices should not be used in proximity to operating X-ray equipment; and that experimentation should not be conducted with radioactive materials in combination with the alleged Orgone Energy, as "it is dangerous to life," which representations and suggestions were false and misleading since they conveyed the impression and belief that the alleged Orgone Energy was a powerful form of energy, particularly when in contact with emanations from radioactive material and roentgen rays, whereas the alleged Orgone Energy was not a powerful form of energy, was nonexistent, and was not "dangerous to life";

(2) Some of the accompanying labeling contained a photograph with a caption conveying the false and misleading impression that the photograph was an actual photograph of the alleged Orgone Energy;

(3) Some of the accompanying labeling contained photographs with captions conveying the false and misleading impression that the photographs were ones showing excited orgone energy fields;

(4) The labeling of the devices, namely, the above-mentioned accompanying labeling, contained false and misleading representations and suggestions that the devices were outstanding therapeutic agents; that they were preventive of, and beneficial for use in, all diseases and disease conditions, and effective in particular in the cure, mitigation, treatment, and prevention of cancer, anemia, pernicious anemia, headaches, cancer

tumor of breasts, influenza, acute and chronic colds, grippe, hay fever, asthma, rheumatism, arthritis, old resilient ulcers, varicose ulcers, duodenal ulcers, chronic illnesses, bruises, cuts, lesions, abrasions, wounds, healing of wounds, burns, bedsores, sinusitis, purulent frontal sinusitis, migraine, neuritis, vascular hypertension, cardiovascular hypertension, high blood pressure, low blood pressure, decompensated heart disease, brain tumors, arteriosclerosis, arteriosclerotic heart disease, apoplectic attacks, skin inflammation, conjunctivitis, sterilization of wounds, immobilization of vaginal bacteria, chronic fatigue, undernourishment, diabetes, angina pectoris, constipation, Basedow's disease, abscesses, chronic diarrhea, chronic bronchitis, gastric ulcer, putrefaction of the intestines, inflammation of the eyeball, hemorrhage of the throat, paradentosis, lichenoid eczema, osteoporosis, thrombophlebitis, compound fracture, Buerger's disease, ichthyosis, epilepsy, multiple sclerosis, chorea, cancer pains, raising hemoglobin, elimination of cancer tumors, tumors easily destroyed, lung cancer, inoperable cancer of esophagus, prevention of metastasis, leukemia, fistula, *Trichomonas vaginalis*, cutaneous abscesses, underweight, pregnancy, tumors, infection, pneumonia, rheumatic fever, hypertension, cut finger, tissue degeneration, blood degeneration, "myodegeneratio cordis," prostatitis, myocardial infarction, intestinal trouble, mediastinal malignancy, and diabetic neuritis; counteracts nuclear radiation, chills, and low resistance; pneumonia preventive; prevents burn blisters; and for shock, epidemics, blood, and tissues.

DISPOSITION: A "Response" was submitted by Defendant Wilhelm Reich, on 2–25–54, in which he denied the jurisdiction of the court to deal with and inquire into the realm of basic research and "Basic Natural Law."

On 3–19–54, all of the defendants having failed to answer Requests for Admissions, and having failed to appear or answer the Complaint for Injunction, the court entered a decree of permanent injunction against the defendants by default, restraining them from introducing into interstate commerce any *Orgone Energy Accumulator* devices adulterated or misbranded as charged above; or doing any act with respect to the devices, while held for sale after shipment in interstate commerce, which would result in the devices becoming adulterated or misbranded in any respect. The decree further provided:

"(1) That all orgone energy accumulator devices, and their labeling, which were shipped in interstate commerce and which (a) are on a rental basis, or (b) otherwise owned or controlled by any one of the defendants, or by the defendants, be recalled by the defendants to their place of business at Rangeley, Maine; and

"(2) That the devices referred to in (1) immediately above, and their parts, be destroyed by the defendants or, they may be dismantled and the materials from which they were made salvaged after dismantling; and

"(3) That the labeling referred to in paragraph (1), just above, except those items for which a specific purchase price was paid by their owners, be destroyed by the defendants; and

"(4) That all parts or portions of orgone accumulator devices shipped in interstate commerce and returned to Rangeley, Maine, or elsewhere, and awaiting repair or re-shipment be destroyed by the defendants, or, they may be dismantled and the materials from which they were made salvaged after dismantling; and

"(5) That all copies of the following items of written, printed, or graphic matter, and their covers, if any, which items have constituted labeling of the article of device, and which contain statements and representations pertaining to the existence of orgone energy, its collection by, and accumulation in,

orgone energy accumulators, and the use of such alleged orgone energy by employing said accumulators, in the cure, mitigation, treatment, and prevention of disease, symptoms, and conditions:

The Discovery of the Orgone by Wilhelm Reich
Vol. I—The Function of the Orgasm
Vol. II—The Cancer Biopathy
The Sexual Revolution by Wilhelm Reich
Ether, God and Devil by Wilhelm Reich
Cosmic Superimposition by Wilhelm Reich
Listen, Little Man by Wilhelm Reich
The Mass Psychology of Fascism by Wilhelm Reich
Character Analysis by Wilhelm Reich
The Murder of Christ by Wilhelm Reich
People in Trouble by Wilhelm Reich

shall be withheld by the defendants and not again employed as labeling; in the event, however, such statements and representations, and any other allied material, are deleted, such publications may be used by the defendants; and

"(6) That all written, printed, and graphic matter containing instructions for the use of any orgone energy accumulator device, instructions for the assembly thereof, all printed, and other announcements and order blanks for the items listed in the paragraph immediately above, all documents, bulletins, pamphlets, journals, and booklets entitled in part, as follows: CATALOGUE SHEET, PHYSICIAN'S REPORT, APPLICATION FOR THE USE OF THE ORGONE ENERGY ACCUMULATOR, ADDITIONAL INFORMATION REGARDING SOFT ORGONE IRRADIATION, ORGONE ENERGY ACCUMULATOR ITS SCIENTIFIC AND MEDICAL USE, ORGONE ENERGY BULLETIN, ORGONE ENFRGY EMERGENCY BULLETIN, INTERNATIONAL JOURNAL OF SEX-ECONOMY AND ORGONE RESEARCH, INTERNATIONALE ZEITSCHRIFT FUR ORGONOMIE, EMOTIONAL PLAGUE VERSUS ORGONE BIOPHYSICS, ANNALS OF THE ORGONE INSTITUTE, and ORANUR EXPERIMENT, but not limited to those enumerated, shall be destroyed; and

"(7) That the directives and provisions contained in paragraphs (1) to (6) inclusive, above, shall be performed under the supervision of employees of the Food and Drug Administration, authorized representatives of the Secretary of Health, Education, and Welfare; and

"(8) That for the purposes of supervision and securing compliance with this decree the defendants shall permit said employees of the Food and Drug Administration, at reasonable times, to have access to and to copy from, all books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or under the control of said defendants, including all affiliated persons, corporations, associations, and organizations, at Rangeley, Maine, or elsewhere, relating to any matters contained in this decree. Any such authorized representative of the Secretary shall be permitted to interview officers or employees of any defendant, or any affiliate, regarding any such matters subject to the reasonable convenience of any of said officers or employees of said defendants, or affiliates, but without restraint or interference from any one of said defendants; and

"(9) That the defendants refrain from, either directly or indirectly, in violation of said Act, disseminating information pertaining to the assembly, construction, or composition of orgone energy accumulator devices to be employed for therapeutic or prophylactic uses by man or for other animals."

Subsequently, on 5–5–54, a petition for leave to intervene in the above injunction case was filed in the United States District Court for the District of Maine on behalf of 15 physicians from New York, New Jersey, and Pennsylvania, who employed Orgonomy in their practices.

The petition prayed that the above default decree be vacated and that the applicants be granted leave to serve and file answers to the complaint. The application was based upon the contention that the applicants were and might be

bound by the decree; that the named defendants in the complaint inadequately represented applicants' interest; that the applicants were so situated that property under the control of the court might be disposed of and applicants would be adversely affected thereby; and, that the rights of the applicants rested upon claims or defenses which were identical in questions of law and fact with those in the main action.

The application was denied by the court on 11–17–54, with the following opinion (17 F. R. D. 96):

CLIFFORD, *District Judge:* "This action comes before this Court upon an application for intervention, filed on May 5, 1954, by Elsworth F. Baker, K. M. Bremer, Philip Gold, Sidney Handelman, Morton Herskowitz, Charles I. Oller, Chester M. Raphael, Michael Silvert, Victor A. Sobey, William F. Thorburn, Oscar Tropp, Simeon J. Tropp, Eileen Walkenstein, James A. Willie and Albert I. Duvall, hereinafter referred to as the applicants. They seek to intervene in the above-entitled action, in which the defendants defaulted and a decree of injunction was entered on March 19, 1954.

"A brief history of that case, hereinafter referred as the original proceeding, is essential to an understanding of this application. On February 10, 1954, a complaint for injunction was filed by the United States of America against the named defendants under section 302 (a) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 332 (a)) to restrain violations of section 301 (a) and (k) (21 U. S. C. 331 (a) and (k)) of said Act.

"The defendant, the Wilhelm Reich Foundation, was a Maine corporation having its principal place of business at Rangeley, Maine. Defendant, Wilhelm Reich, was an individual residing in Rangeley and was the moving spirit in the above Foundation and its activities; Ilse Ollendorff, otherwise known as Mrs. Wilhelm Reich, also resided at Rangeley and was actively engaged in the conduct of the Foundation, and other affiliated activities of Wilhelm Reich.

"The complaint alleged in general that the said defendants were manufacturing and introducing into interstate commerce certain devices referred to by them as orgone energy accumulators, and were representing in their labelling that such devices were therapeutic agents which were beneficial in the cure, mitigation, treatment, and prevention of innumerable diseases and conditions, including such serious and chronic ailments as cancer, anemia, arteriosclerosis, brain tumors, diabetes, gastric ulcers, Buerger's Disease, and leukemia. It was further alleged that such devices were not effective in the treatment of such diseases and conditions and that, therefore, they were misbranded within the meaning of 21 U. S. C. 352 (a); it was also alleged that they were adulterated within the meaning of 21 U. S. C. 351 (c) in that their strength differed from, and their quality fell below, that which they were purported and represented to possess. The complaint prayed that the defendants, their officers, agents, servants, employees, attorneys, all corporations, associations, and organizations, and all persons in active concert or participation with any of them be perpetually enjoined from introducing or delivering for introduction into interstate commerce any such orgone energy accumulator devices and their accessories or any similar article allegedly so misbranded and adulterated. The complaint also prayed that the named defendants be perpetually enjoined from doing or causing any act, oral, written, or otherwise with respect to any kind of orgone energy accumulator device while held for sale after shipment in interstate commerce, which results in said article being misbranded or adulterated within the meaning of the above designated sections of the Act.

"Service of a copy of the complaint and summons were duly made upon each of the three defendants on February 10, 1954. No appearance was entered by any of the defendants, nor was an answer filed by them. However, under date of February 25, 1954, defendant Wilhelm Reich sent to the Presiding Judge of this Court a letter purporting to be a concise statement of his position which was more fully set forth in an enclosed lengthy document entitled by him as the 'Response.' The letter reads as follows:

DEAR JUDGE CLIFFORD:

I am taking the liberty of transmitting to you my "Response" to the complaint filed by the Food and Drug Administration regarding the Orgone Energy Accumulator. My "Response" summarizes my standpoint as a natural scientist who deals with matters of basic natural law. It is not in my hands to judge the legal aspects of the matter.

My factual position in the case as well as in the world of science of today does not permit me to enter the case against the Food and Drug Administration, since such action would, in my mind, imply admission of the authority of this special branch of the Government to pass judgment on primordial, pre-atomic cosmic orgone energy.

I, therefore, rest the case in full confidence in your hands.

Sincerely yours,

/S/ WILHELM REICH, M. D.

"On February 26, 1954, certain requests for admissions were propounded by the United States and served upon each of the named defendants requesting answer thereto within ten days after such service. No appearance, acknowledgment, or answer was made, at any time, by any of the defendants in reply thereto. Twenty-one days later, namely, on March 19, 1954, upon requests by the United States, default of each of the named defendants was duly entered by the Clerk of this Court. On the same date, upon motion for Default Judgment by the Government, a Decree of Injunction against the named defendants was entered, as prayed for, enjoining them and their officers, agents, servants, employees, attorneys, all corporations, associations, and organizations, and all persons in active concert, or participation with any of them from the practices set out in the complaint.

"On March 22, 1954, certified copies of the decree were served on the three named defendants. At the same time, copies were either served upon or mailed to several other persons at Rangeley, Maine, and at nearby Farmington, who were employees or contractors for the defendants in the manufacture and distribution of these devices.

"Copies of the decree were also mailed to each of the applicants. These individuals are duly licensed physicians, nearly all of whom specialize in the practice of psychiatry in the New York City, Philadelphia, and New Jersey area. As it appears from their affidavits, they have no legal relationship with any of the named defendants. Apparently, copies of the decree were mailed to them because of their activity in the field of Orgonomy. They all believe in the existence and validity of the alleged science, employ its principles and use orgone energy accumulators in their professional practices, and many of them had within recent years studied matters relating to Orgonomy under Dr. Reich. It does not appear, however, from their affidavits and answer, nor do they contend, that they were engaged in the manufacture and distribution in interstate commerce of orgone energy accumulators.

"The application for intervention was filed on May 5, 1954, approximately two months after the entry of the default decree, and counsel for the Government and the applicants were heard thereon on the same day.

"On June 7, 1954, the Government filed a statement and certain documents in opposition to this motion to intervene, and served copies by mail upon counsel for the applicants. Among the documents submitted by the Government was a telegram sent by Ilse Ollendorff, clerk of the Wilhelm Reich Foundation, which read as follows:

1954 MAR. 30

PETER MILLS
DISTRICT ATTORNEY,
FEDERAL COURT HOUSE, PORTLAND, ME.

The Wilhelm Reich Foundation is far advanced in preparing full compliance with injunction of March 19, 1954 Stop An exact account of measures taken and still in progress will be sent to your office for your information.

THE WILHELM REICH FOUNDATION,
Ilse Ollendorf, Clerk.

Also, briefs were subsequently submitted for consideration by this Court.

"The right to intervene is governed generally by Rule 24 of the Federal Rules of Civil Procedure, the pertinent portions of which read as follows:

> (a) Intervention of right. Upon timely application anyone shall be permitted to intervene in an action: * * * (2) When the representation of the applicant's interest by existing parties is or may be inadequate and the applicant is or may be bound by a judgment in the action; * * *
>
> (b) Permissive Intervention. Upon timely application anyone may be permitted to intervene in an action: * * * (2) When an applicant's claim or defense and the main action have a question of law or fact in common. * * * In exercising its discretion the court shall consider whether intervention will unduly delay or prejudice the adjudication of the rights of the original parties. * * *

"Principally, the applicants contend that they are members of a class against whom, along with the named defendants, the original proceeding was filed; that they were not given notice of the action by process; that they were not adequately represented by the named defendants in that proceeding; that they are bound by the decree in that it was designed to and actually does interfere with basic functions of their practice of medicine; and that this is a right which they should have had the opportunity to protect in the original proceeding. They conclude, therefore, that having an absolute right to intervene under Rule 24 (a) (2), intervention should be allowed even after a final judgment has been entered because there is no other way in which said right could be protected.

"Independently of Rule 24 (a) (2), they contend that their claims and defenses involved questions of law and fact identical with those of the original proceeding and, therefore, permission to intervene should be granted them under Rule 24 (b) (2).

"Although the right to intervene under Rule 24 (a) (2) must be predicated upon the two factors referred to therein, the crucial prerequisite seems to be whether or not the applicant may be 'bound' by the judgment in the action. *4 Moore's Fed. Practice*, 2d Ed., Par. 24.08; see note, *63 Yale Law Journal* 408. It is generally held that an applicant may be 'bound' within the meaning of Rule 24 (a) (2) only when he may be subject to *res judicata*. *Stuphen Estates* v. *United States*, 324 U. S. 19; *Innis, Speiden & Co.* v. *Food Machinery Corp.*, 2 F. R. D. 261; *Owen* v. *Paramount Productions*, 41 F. Supp. 557; cf. *Cameron* v. *President and Fellows of Harvard College*, 157 F. 2d 993. The rationale is that the protection afforded by intervention of right is not essential to one who will have another legal remedy available after judgment. Note, *63 Yale Law Journal*, supra, 411. And, as a general rule, no person or those in privity with him is bound by an *in personam* judgment arising from an action in which he was neither served with process nor given an opportunity to litigate his claims or defenses. *Pennoyer* v. *Neff*, 95 U. S. 714; *Hansberry* v. *Lee*, 311 U. S. 32. The effect of a judgment in a class action, however, is a recognized exception to this latter rule. *Hansberry* v. *Lee*, supra; *U. S.* v. *American Optical Co.*, 97 F. Supp. 66; *Restatement of the Law, Judgments*, Sec. 86. But it is only in a so-called true class action that the judgment is conclusive upon the absent members. *System Federal No. 94* v. *Reed*, 180 F. 2d 991; *Waybright* v. *Columbian Mutual Life Ins. Co.*, 122 F. 2d 245. A judgment in a 'hybrid' action is conclusive upon absent members only as to their rights in the res; in a 'spurious' class action, only on the parties before the court. See *46 Columbia L. Rev.* 818, 824.

"It is apparent that the applicants have assumed that the original proceeding was a true class action, the judgment in which would be binding upon them even though they were not designated parties to it. Concerning what was involved in the original proceeding, this is the only basis upon which they could possibly hope to succeed in their attempt to intervene as a matter of right. Indeed, there is authority that Rule 24 (a) (2) is limited in its application to technical representative actions, such as the true and hybrid class suits provided for in Rule 23 (a). *U. S.* v. *Columbia Gas & Electric Corp.*, 27 F. Supp. 116; *4 Moore's Federal Practice*, 2d Ed. Par. 24.08; see also Note, *63 Yale Law Journal*, supra, n. 16.

"The applicants, however, have in the opinion of this Court misconceived the basis and nature of the original proceeding and are clearly unwarranted

in their contentions with regard to intervention as a matter of right under Rule 24 (a) (2). The original proceeding was an *in personam* action brought solely against three specifically designated persons for the purpose of enjoining them from manufacturing and distributing in interstate commerce orgone energy accumulators which were adulterated and misbranded within the meaning of the Food and Drug Act. The very purpose of the Act is to keep interstate commerce free from deleterious, adulterated and misbranded articles of specified types to the end that the public health and safety might be advanced. *United States* v. *Walsh*, 331 U. S. 432. And the prohibition of the stated activity of the named defendants was the sole object which the Government sought to accomplish by its action.

"Since the applicants were not engaged in the manufacture and distribution in interstate commerce of orgone energy accumulators, nor were they in any respect legally associated with the named defendants, the named defendants were properly the only parties before this Court in the original proceeding. Especially is this so when the applicants themselves frankly state in their briefs that the only purpose for their application for intervention is to establish the existence and validity of Orgonomy, a matter which was collateral to the main issue in the original proceeding. Accordingly, persons who are not parties to an injunction, nor in privity with them, and whose rights have not been adjudicated therein are not bound by a decree and cannot be held liable for acts done contrary thereto even though the decree assumes to bind them. *Swetland* v. *Curry*, 188 F. 2d 841; *Kean* v. *Hurley*, 179 F. 2d 888; *Chase National Bank* v. *City of Norwalk*, 291 U. S. 431; *Alemite Mfg. Corp.* v. *Staff*, 42 F. 2d 832; *Scott* v. *Donald*, 165 U. S. 107.

"The fact that the applicants may subject themselves to contempt proceedings if they act in concert with the named defendants in violating the terms of the decree does not alter the basic nature of the original proceeding. The provision relating to 'officers, agents, servants, employees, etc. . . .' was inserted merely to make the decree effective as against the named defendants, adopting to a great extent the language of Rule 65(d) of the Federal Rules of Civil Procedure. Such clauses are a standard provision in injunction decrees and do not impose any liability which would not exist without them. *Alemite Mfg. Corp.* v. *Staff*, supra; *Regal Knitwear Co.* v. *Board*, 324 U. S. 9; *Chase National Bank* v. *City of Norwalk*, 291 U. S. 431; *United States* v. *American Optical Co.*, 97 F. Supp. 66. As stated in *Regal Knitwear Co.* v. *Board*, Supra, 14:

> This [Rule 65 (d)] is derived from the common-law doctrine that a decree of injunction not only binds the parties defendant but also those identified with them in interest, in "privity" with them, represented by them or subject to their control. In essence it is that defendants may not nullify a decree by carrying out prohibited acts through aiders and abettors, *although they were not parties to the original proceeding.* [Emphasis supplied.]

"Service of copies of the decree upon the applicants, therefore, was in conformance with Rule 65 (d), putting them on notice that they, like any other person with notice of the decree, are subject to contempt proceedings should they enable the named defendants to circumvent its terms by performing proscribed activities through them. Nevertheless, since they were not parties to the original proceeding, their activity in the field of Orgonomy remains unrestricted even with regard to matters barred by the decree, so long as they act independently of the named defendants. Undoubtedly, however, the applicants will, as a practical matter, be adversely affected by the decree, but that is of no legal consequence, insofar as intervention of right is concerned. *Stuphen Estates* v. *United States*, 324 U. S. 19; *Durkin* v. *Pet Milk Co.*, 14 F. R. D., 374, 378, where the court stated that the 'movants may be indirectly affected by a judgment . . . but they will not be "bound" by the judgment in the sense contemplated by the Rule.' See also *Brotherhood of Locomotive Engineers* v. *Chicago*, M. St. P. & P. R. R., 34 F. Supp. 594, 596; *Kind* v. *Markham*, 7 F. R. D. 265. Therefore, under all the facts and circumstances of this case, this Court is of the opinion that the applicants do not have an absolute right to intervene under Rule 24 (a) (2) because the default decree is not and cannot be *res judicata* as to them.

"Furthermore, under both Rule 24 (a) (2) and Rule 24 (b) (2) an application for intervention must be timely made. What constitutes timeliness is entrusted to the discretion of the Court. Permissive intervention under Rule 24 (b) (2) is very largely a matter of trial convenience and should be made at an early stage of the main proceedings to be of any measurable value. Intervention under Rule 24 (a) (2), however, involves something more than trial convenience and might well be allowed at a stage in the proceedings when permissive intervention would be denied. *Cameron* v. *President and Fellows of Harvard College*, 157 F. 2d 993. Although the determination of timeliness involves a consideration of a number of factors and the time element alone is not controlling, a strong showing must be made by the applicants in order to be allowed to intervene after the entry of a final judgement. See *4 Moore's Federal Practice* 2d Ed. Par. 24.13.

"The only factor stressed by the applicants in this regard is that they have no other way in which their rights could be protected, citing *Pellegrino* v. *Nesbit*, 203 F. 2d 463; *Wolpe* v. *Peretsky*, 144 F. 2d 505; *United States Casualty Co.* v. *Taylor*, 64 F. 2d 521; *Western Union Telegraph Co.* v. *IBEW, Local Union No. 134, et al*, 133 F. 2d 955. The premise upon which the applicants base their contention is erroneous. As this Court has already determined, the applicants are not 'bound' by the original proceeding and, therefore, their rights with regard to Orgonomy have never been adjudicated. Consequently, the applicants' contention in this respect is without merit and the cases cited by them are, therefore, inapplicable.

"Moreover, considering that the application for intervention was filed some two months after the entry of the default decree and one of the named defendants has indicated to the United States Attorney for the District of Maine that they have substantially complied with its terms, and under all of the other facts and circumstances of this case, this Court, in the exercise of its discretion, is of the opinion that the application for intervention was not timely made under the provisions of either Rule 24 (a) (2) or 24 (b) (2).

"It is therefore ORDERED, ADJUDGED, and DECREED that the application for intervention filed by the applicants on May 5, 1954, be and hereby is DENIED."

Applicants moved for a stay of execution of the decree of injunction pending appeal to the United States Court of Appeals for the First Circuit. This motion was granted by the district court on 1–18–55, as applying to the destruction of books and apparatus on 1–18–55, and was denied as to the rest of the terms of the decree.

Applicants thereafter appealed the denial of the application to intervene; and, on 5–11–55, the United States Court of Appeals for the First Circuit affirmed the decision of the district court (221 F. 2d 957).

Applicants thereafter filed motions for a stay of enforcement of the decree of injunction in the United States District Court for the District of Maine, in the United States Court of Appeals for the First Circuit, and in the United States Supreme Court, pending a petition for a writ of certiorari. All of these motions were subsequently denied.

On 10–10–55, the United States Supreme Court denied applicants' petition for a writ of certiorari.

5392. Orgone Energy Accumulators. (Inj. No. 261.)

Information Filed: On 7–15–55, in the District of Maine, the United States attorney instituted criminal contempt proceedings by filing an information and an application for an order to show cause why Wilhelm Reich Foundation, a Maine corporation, Rangeley, Maine, Wilhelm Reich, an individual, Rangeley, Maine, and Michael Silvert, an individual, New York, N. Y., should not be punished for criminal contempt of the permanent injunction which had been entered against Wilhelm Reich Foundation, Wilhelm Reich, and Ilse Ollen-

dorff, on 3–19–54, as reported in the foregoing notice of judgment on drugs and devices, No. 5391.

An amendment to the information was filed on 9–23–55.

CHARGE: The information alleged that, since the entry of the decree, Wilhelm Reich Foundation and Wilhelm Reich had failed, as directed and ordered in the decree of injunction: (1) to recall to Rangeley, Maine, all *Orgone Energy Accumulator* devices and their labeling which were shipped in interstate commerce either on a rental basis or otherwise owned or controlled by the defendants and to dismantle for salvage or destroy those devices and their parts and to destroy the labeling; (2) to dismantle for salvage or destroy all *Orgone Energy Accumulator* devices, accessories, components, and parts that had been shipped in interstate commerce and that had been returned to Rangeley, Maine, where they were awaiting repair, reshipment, or other disposition; (3) to withhold and not again employ as labeling items of written, printed, and graphic matter and their covers, if any, which had constituted labeling of the devices and which contained statements and representations pertaining to the existence of Orgone energy, its collection by, and accumulation in, the device, and the use of the alleged energy by employing the device in the cure, mitigation, treatment, and prevention of disease, symptoms, and conditions as enumerated specifically in the decree; (4) to destroy all written, printed, and graphic matter containing instructions for the use or assembly of the device, all announcements and order blanks for the items in (3) above, and all documents, bulletins, phamplets, journals, and booklets, as specifically enumerated in the decree; and (5) to permit employees of the Food and Drug Administration, at reasonable times, to have access to, and copy from, all books, ledgers, accounts, correspondence, memoranda, and other records and documents in their possession and control relating to matters contained in the injunction decree.

The information alleged further that the following telegram was sent to the United States Attorney for the District of Maine on 3–30–54: "The Wilhelm Reich Foundation is far advanced in preparing full compliance with injunction of March 19, 1954 Stop An exact account of measures taken and still in progress will be sent to your office for your information"; that despite the telegram and in defiance of the injunction, Wilhelm Reich had refused to comply with its terms at any time, and on 12–30–54, in Tucson, Ariz., and on 6–6–55, at Rangeley, Maine, had refused to talk to, be interviewed by, and furnish information to, inspectors of the Food and Drug Administration; and that Wilhelm Reich Foundation had refused also at all times to comply with the terms of the injunction.

It was alleged also that Michael Silvert had been served with a copy of the injunction on 4–1–54, and was one of the applicants for intervention in the above-mentioned notice of judgment on drugs and devices, No. 5391; and that within four days after the order of the court denying the stay of execution of the decree of injunction, he shipped from Rangeley, Maine, to New York, N. Y., a number of the devices, accessories, components, and parts, along with various items of written, printed, and graphic matter which constituted labeling.

It was alleged further that Michael Silvert, in concert with Wilhelm Reich and Wilhelm Reich Foundation: (1) continued to carry on the business transactions and affairs of Wilhelm Reich and Wilhelm Reich Foundation; (2) continued to offer for sale and sell various items of written, printed, and graphic

matter which fell within the proscriptions of the decree; (3) collected rentals for the devices and ordered the return of the devices to New York, N. Y.; and (4) refused to furnish, upon reasonable requests, to inspectors of the Food and Drug Administration, information, access to, and permission to, copy from, the books, ledgers, accounts, correspondence, and memoranda of Wilhelm Reich and Wilhelm Reich Foundation.

DISPOSITION: An order to show cause was entered on 7–15–55; and, on 7–26–55, the defendants pleaded not guilty. The Government, on 9–23–55, made a motion to amend the information, which was granted by the court on 10–11–55. On 10–18–55, the defendants pleaded not guilty to the information as amended.

The case came on for trial before a jury on 5–3–56. Wilhelm Reich and Michael Silvert refused to appear, and the court issued bench warrants to have them brought into court, after which the trial continued. The trial was concluded on 5–7–56, with a return by the jury of a verdict of guilty against the defendants for criminal contempt of the injunction. The court, on the same day, fined Wilhelm Reich $500 and Michael Silvert $300 for contempt of court arising out of their refusal to appear for trial, and postponed sentence until 5–25–56, for violation of injunction. On that day, the court sentenced Wilhelm Reich to 2 years in jail, Michael Silvert to 1 year and 1 day in jail, and fined Wilhelm Reich Foundation $10,000.

The defendants appealed to the United States Court of Appeals for the First Circuit on 6–4–56; and, on 12–11–56, this court affirmed the judgment of the district court with the following opinion (239 F. 2d. 134):

WOODBURY, *Circuit Judge:* "The United States, on February 10, 1954, filed a complaint under § 302 (a) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1043, 21 U. S. C. § 332 (a), in the United States District Court for the District of Maine asking for an injunction restraining the Wilhelm Reich Foundation, a Maine corporation, and Wilhelm Reich and Ilse Ollendorff, individuals residing in Rangeley, Maine, from violating § 301 (a) and (k) of the above Act by either introducing, or causing the introduction into interstate commerce, or, while being held for sale after shipment in interstate commerce doing anything resulting in the misbranding of, certain devices known as 'orgone energy accumulators,'* which it was alleged were adulterated within the meaning of § 501 (c) of the Act and misbranded within the meaning of § 502 (a) thereof. Service of the complaint and summons was duly made on the defendants on the same day that the complaint was filed.

"The defendants entered no appearances and filed no answers. Indeed, in a letter to the judge of the court below dated February 25, 1954, the defendant, Dr. Wilhelm Reich, indicated unmistakably that he, at least, had no intention of filing either an appearance or an answer. Dr. Reich wrote to the court in part:

> My factual position in the case as well as the world of science of today does not permit me to enter the case against the Food and Drug Administration, since such action would, in my mind, imply admission of the authority of this special branch of the government to pass judgment on primordial preatomic cosmic orgone energy.

"On the day after this letter was written requests for admissions were propounded by the United States and served on each of the defendants. These requests were ignored, and on March 19, 1954, upon request of the United States, the default of each defendant was entered by the clerk of the court below. On the same day the United States moved for default judgment, its motion was granted, and the court immediately entered a decree of injunction as prayed for in the complaint. By the terms of this injunction the

*In their commonest form these are box-like structures in which the patient sits for treatment. It is asserted by the Government that these devices were being falsely held out to the public at large by the defendants as at least beneficial in the treatment of a great number of human ills ranging from cancer to the common cold.

named defendants, and 'each and all of their officers, agents, servants, employees, . . . and all persons in active concert or participation with them or any of them' were 'perpetually enjoined and restrained' from indulging in the practices set out in detail in the complaint. Furthermore all orgone energy accumulators out on a rental basis or otherwise owned or controlled by the defendants were ordered recalled to the defendants' place of business in Rangeley, Maine, and there either destroyed or dismantled for salvage under the supervision of employees of the Food and Drug Administration, and in addition all printed labels and order blanks for orgone energy accumulators, and certain listed descriptive literature pertaining thereto, were ordered destroyed.

"Certified copies of the decree of injunction were served on the named defendants on March 22, 1954, and at the same time copies were either served or mailed to several other persons in the Rangeley area who were either employees of or contractors for the defendants in the manufacture and distribution of the devices. At the same time copies of the decree were also mailed to a number of duly licensed physicians in the New York, New Jersey, and Philadelphia area, most of whom specialized in psychiatry, who were known to have used orgone energy accumulators in the treatment of their patients. Included in this group was the appellant herein, Dr. Michael Silvert.

"On March 30, 1954, the defendant Ilse Ollendorff as clerk of the corporate defendant sent a telegram to the United States Attorney for the District of Maine stating:

> The Wilhelm Reich Foundation is far advanced in preparing full compliance with injunction of March 19, 1954 Stop An exact account of measures taken and still in progress will be sent to your office for your information.

"No further account of measures taken to comply with the injunction was ever sent to the District Attorney, nor does it appear that in fact any such measures ever were undertaken.

"Next, on May 5, 1954, the doctors in the New York-Philadelphia area referred to above, including as we have already noted the appellant Dr. Michael Silvert, applied to the court below for leave to intervene. Their application was denied on November 17, 1954, in accordance with an opinion of the court below of that date reported in 17 F. R. D. 96 (1954). This court affirmed on that opinion *sub nom Baker* v. *United States*, 221 F. 2d 957 (1955).

"We turn now to the case before us which was initiated by the United States Attorney for the District of Maine on July 15, 1955, when, acting under § 302 (b) of the Act, he filed in the court below an information charging the Wilhelm Reich Foundation, Dr. Wilhelm Reich and Dr. Michael Silvert with failing and refusing to obey the injunction of March 19, 1954, and asking for an order to show cause why they should not be adjudged in criminal contempt for their misbehavior. The defendants appeared and filed motions to dismiss, which were denied; the United States moved to amend, its motion was allowed, and the defendants again moved to dismiss and their motions were again denied. They also filed several other motions, all of which were denied, and do not require description or discussion. It will suffice to say that the defendants were given full opportunity for hearing on every occasion.

"Eventually, on May 3, 1956, the defendants, in accordance with their request, were put to trial by jury on their pleas of not guilty. They were found guilty by the jury and thereafter sentenced by the court, the corporation to a fine and the individuals to terms of imprisonment. These appeals are from the respective judgments of sentence.

"The defendants did not contend below and do not urge here that the injunction of March 19, 1954, had in fact been obeyed. On the contrary, they admitted at the trial that no attempt had been made to comply with its terms. Their contention is that the court below had no jurisdiction to issue the injunction. The individual appellants say that they, both individually and acting through the corporate defendant, of which Dr. Reich was the moving and guiding spirit, were engaged in basic scientific research which no agency of the Government had jurisdiction to interfere with or

control, and that furthermore and more specifically, the court below had no jurisdiction to issue the injunction for the reason that it had been procured by fraud and deception practiced upon the court by officers and agents of the Food and Drug Administration. In addition Dr. Silvert contends that he is not bound by the injunction because he was not a defendant in the original suit in which it was issued and had not been served with process therein.

"None of these contentions have any merit.

"We turn first to Dr. Silvert's separate contention. It has been settled law for a long time that one who knowingly aids, abets, assists, or acts in active concert with, a person who has been enjoined in violating an injunction subjects himself to civil as well as criminal proceedings for contempt even though he was not named or served with process in the suit in which the injunction was issued or even served with a copy of the injunction. *In Re Lennon*, 166 U. S. 548, 554 (1897); *Alemite Mfg. Corp.* v. *Staff*, 42 F. 2d 832 (C. A. 2, 1930) and cases cited. See also Rule 65 (d) F. R. Civ. P. The question then is whether Dr. Silvert had actual knowledge of the injunction of March 19, 1954, issued against the Wilhelm Reich Foundation, and Dr. Wilhelm Reich and Ilse Ollendorff personally. There can be no doubt that he did. He was mailed a copy of that injunction when it was issued, he admitted at the trial that he read the injunction when he received it, and moreover he was one of those who moved to intervene in the suit in which it was issued. Thus it is abundantly clear that he knew of its existence and knew its terms.

"The appellants' first jurisdictional contention does not deserve much comment or discussion. Its refutation is obvious from its mere statement. Of course the United States Government has power to forbid and power to take appropriate steps to prevent the transportation in interstate commerce of devices of alleged therapeutic value if they are adulterated or misbranded.

"The appellants' second jurisdictional contention deserves only slightly more extended consideration. There can be no doubt whatever that Congress in § 302 (a) of the Federal Food, Drug, and Cosmetic Act gave the District Court jurisdiction over the subject matter of the original suit. Nor can there be any doubt that the District Court obtained personal jurisdiction over the defendants in that suit by legal service of process upon them in Maine. This jurisdiction, once obtained, certainly would not be terminated by any fraud practiced upon the court by the successful litigant. On the contrary, the Court's jurisdiction would necessarily have to continue in order to permit the court to entertain an application by the victims of a successful litigant's fraud to vacate the injunction through the remedies and procedures for relief outlined in detail in *Hazel-Atlas Glass Co.* v. *Hartford-Empire Co.*, 322 U. S. 238 (1944).

"And the remedies and procedures available to a defrauded litigant certainly do not include refusal to obey an injunction. It is too well settled to require a lengthy citation of cases that an injunction, temporary or permanent, must be obeyed as long as it is in force and effect. *Howat* v. *Kansas*, 258 U. S. 181 (1922); *United States* v. *United Mine Workers of America*, 330 U. S. 258, 289, et seq. (1947) and cases cited. Nor is this rule a mere technical quirk of procedure, for as the Supreme Court pointed out in *Gompers* v. *Bucks Stove & Range Co.*, 221 U. S. 418, 450 (1911):

> If a party can make himself a judge of the validity of orders which have been issued, and by his own act of disobedience set them aside, then are the courts impotent, and what the Constitution now fittingly calls the "judicial power of the United States" would be a mere mockery.

See also the remarks made by Mr. Justice Frankfurter at the bottom of page 311 and the top of page 312 of his concurring opinion in the *United Mine Workers case, supra.*

"It follows that the court below did not err in refusing to permit the defendants at their trial for contempt to show in their defense that officers and agents of the Food and Drug Administration had procured the injunction of March 19, 1954, by fraud perpetrated upon the court.

"Although the court's refusal to permit the defendants to show fraud in procuring the injunction is the only error asserted by them to have occurred

at their trial, we have nevertheless, because the defendants were not represented by counsel in the court below and only partially on appeal, examined the record with particular care. We find ample evidence that Dr. Reich and the Wilhelm Reich Foundation deliberately refused to obey the injunction and that Dr. Silvert aided and abetted them in flouting it. Nor do we find any erroneous rulings of law. Indeed, it is evident from the record that throughout the trial the presiding judge solicitously protected the appellants' rights and gave them full opportunity to present every defense available to them under the law.

"Judgment will be entered affirming the judgments of the District Court."

The United States court of appeals, on 12–18–56, after a motion by the defendants, ordered a stay of mandate pending an application to the Supreme Court of the United States for a writ of certiorari. On 1–10–57, defendants filed a petition for a writ of certiorari in the Supreme Court of the United States, which petition was denied on 2–25–57.

Defendants filed in the district court, on 2–27–57, motions to strike the sentences imposed against them for violation of the injunction. These motions were denied on 3–11–57. Thereupon, Wilhelm Reich and Michael Silvert filed motions for reduction or suspension of the sentences of imprisonment, and these motions were denied on or about 4–30–57.

5393. Rubber prophylactics (2 seizure actions). (F. D. C. Nos. 40319, 40327. S. Nos. 60–173/4 M, 72–817 M, 72–820 M.)

QUANTITY: 127 gross at Chicago, Ill.

SHIPPED: Between 2–28–57 and 5–16–57, from Atlanta, Ga., by W. H. Reed & Co., Inc.

RESULTS OF INVESTIGATION: Examination showed that from 3.5 percent to 13 percent of the article was defective in that it contained holes.

LIBELED: 6–10–57 and 6–13–57, N. Dist. Ill.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported to possess; and 502 (a)—the label statement "Prophylactics" was false and misleading as applied to a product containing holes.

DISPOSITION: 7–9–57. Default—destruction.

5394. Rubber prophylactics. (F. D. C. No. 40213. S. No. 72–800 M.)

QUANTITY: 34 gross ctns., each ctn. containing 12 boxes, each box containing 4 tins, and each tin containing 3 *rubber prophylactics*, at Chicago, Ill.

SHIPPED: 2–27–57, from Atlanta, Ga., by W. H. Reed & Co., Inc.

LABEL IN PART: (Tin) "This package contains three Golden Pheasant Prophylactics Insist on the genuine (Made in W. Germany) Golden Pheasant."

RESULTS OF INVESTIGATION: Examination showed that 5.4 percent of the article was defective in that it contained holes.

LIBELED: 5–17–57, N. Dist. Ill.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the label statement "Prophylactics" was false and misleading as applied to a product which contained holes.

DISPOSITION: 6–19–57. Default—destruction.

5395. Rubber prophylactics. (F. D. C. No. 40307. S. No. 57–627 M.)

QUANTITY: 32 gross at Tampa, Fla.

SHIPPED: 2–19–57, from Atlanta, Ga., by W. H. Reed & Co., Inc.

LABEL IN PART: "Golden Pheasant One Lubricated Golden Pheasant Prophylactic Insist on the genuine. Mfgd. in W. Germany Packed by W. H. Reed & Co., Atlanta, Ga."

RESULTS OF INVESTIGATION: Examination showed that 3.8 percent of the article was defective in that it contained holes.

LIBELED: 6–7–57, S. Dist. Fla.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported to possess; and 502 (a)—the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: 7–19–57. Default—destruction.

5396. **Rubber prophylactics.** (F. D. C. No. 40315. S. No. 72–819 M.)

QUANTITY: 24 ctns. at Chicago, Ill.

SHIPPED: 2–7–57, from Atlanta, Ga., by W. H. Reed & Co., Inc.

LABEL IN PART: (Ctn.) "Golden Pheasant * * * One Dozen"; (tin) "This package contains three Golden Pheasant Prophylactics."

RESULTS OF INVESTIGATION: Examination showed that 3.2 percent of the article was defective in that it contained holes.

LIBELED: 6–7–57, N. Dist. Ill.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported to possess; and 502 (a)—the label statement "Prophylactics" was false and misleading as applied to a product containing holes.

DISPOSITION: 7–10–57. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

5397. **Digitoxin tablets.** (F. D. C. No. 40169. S. No. 41–936 M.)

QUANTITY: 1 drum containing 280,600 tablets at Rensselaer, N. Y.

SHIPPED: Digitoxin powder was shipped on 11–2–56, from Newark, N. J.

RESULTS OF INVESTIGATION: Examination showed that the tablets contained not more than 82.9 percent of the declared amount of digitoxin per tablet. The tablets were prepared from the digitoxin powder which was shipped as described above.

LIBELED: 5–16–57, N. Dist. N. Y.

CHARGE: 502 (a)—the statement "Digitoxin . . . . 0.1 mg." on the label of the article, while held for sale, was false and misleading.

DISPOSITION: 7–19–57. Default—destruction.

5398. **Cabbex (desiccated cabbage).** (F. D. C. No. 40176. S. Nos. 42–593 M, 72–901 M.)

QUANTITY: 16 btls. at Denver, Colo., in possession of Strauss Vitamin Store.

SHIPPED: 3–11–57, from Omaha, Nebr.

LABEL IN PART: (Btl.) " One Pound Guardian * * * Cabbex—Cabbage Powder For Cabbage Juice * * * As a supplementary source of nutrients in cabbage take four teaspoonsful daily."

ACCOMPANYING LABELING: Window placard reading "Cabbex Cabbage Juice Concentrate with your Ulcer Diet Full Lb. 3.98."

*See also Nos. 5389, 5391–5396.

LIBELED: 4–30–57, Dist. Colo.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was effective in the treatment for ulcers.

DISPOSITION: 6–10–57. Default—destruction.

DRUGS FOR VETERINARY USE

5399. Cal-Ruphenol. (F. D. C. No. 40295. S. No. 59–056 M.)

QUANTITY: 1 drum containing 65,000 tablets at Philadelphia, Pa., in possession of Cal-Vet Laboratories.

SHIPPED: 4–21–55, from Camden, N. J.

LABEL IN PART: (Drum) "Mannitol * * * with Phenobarbital and Rutin * * * Each tablet contains: Phenobarbital ¼ gr. * * * Mannitol Hexanitrate ½ gr. Rutin 20 mg."

ACCOMPANYING LABELING: Loose labels reading, in part, "Cal-Ruphenol Each tablet contains: Mannitol Hexanitrate 0.5 gr. Phenobarbital 0.25 gr. * * * Rutin 20 mg."

RESULTS OF INVESTIGATION: The loose labels were printed locally for the consignee. They were used in the regular course of business by the consignee in repacking the bulk tablets into containers holding either 1,000 tablets or 100 tablets.

LIBELED: 5–29–57, E. Dist. Pa.

CHARGE: 502 (a)—while held for sale, the labeling of the article, namely, the label used on the repacked tablets, accompanying the article, contained representations that the article was an adequate and effective treatment for preventing and treating chorea in dogs, whereas the article was not an adequate and effective treatment for such purposes.

DISPOSITION: 8–23–57. Default—destruction.

5400. Dr. Mayfield Liquid Roundwormer. (F. D. C. No. 40110. S. No. 56–822 M.)

QUANTITY: 11 1-pt. btls., 18 1-qt. btls., and 1 1-gal. btl. at Mabel, Minn.

SHIPPED: Between 10–31–56 and 2–27–57, from Charles City, Iowa, by Dr. Mayfield Laboratories.

LABEL IN PART: "Dr. Mayfield Liquid Roundwormer * * * Active Ingredients: Piperazine Hexahydrate 38% Inert Ingredients: Water 62%."

LIBELED: 3–29–57, Dist. Minn.

CHARGE: 502 (a)—when shipped, the bottle labels of the article contained false and misleading representations that the article was an adequate and effective treatment for the removal of cecal worms from chickens; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

DISPOSITION: 6–25–58. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 5381 TO 5400

PRODUCTS

[1] (5385) Prosecution contested. Contains opinions of the courts.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5385) Prosecution contested. Contains opinions of the courts.
[2] (5391) Injunction contested. Contains opinions of the court.
[3] (5392) Prosecution contested. Contains opinion of the court.

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FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5401–5420

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve seizure proceedings which were terminated with the entry of consent or default decrees of condemnation. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *February 2, 1959.*

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*For presence of a habit-forming narcotic without warning statement, see No. 5401; omission of, or unsatisfactory, ingredients statements, No. 5403; failure to bear a label containing an accurate statement of the quantity of the contents, No. 5403; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5403.

492730—59

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5401–5420

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, or its purity or quality fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5401. Elixir Albephen, Merhistin expectorant, elixir Merbutal, and elixir Duophen. (F. D. C. No. 40337. S. Nos. 67–474 M, 67–476 M, 67–478/9 M.)

QUANTITY: 20 1-gal. btls. and 43 1-pt. btls. of *elixir Albephen;* 68 1-pt. btls. of *Merhistin expectorant;* 6 1-gal. btls. and 94 1-oz. btls. of *elixir Merbutal;* and 246 1-oz. btls. of *elixir Duophen*, at Silver Spring, Md., in possession of Meredyth Co.

SHIPPED: Between 5–5–54 and 1–30–57, from Philadelphia, Pa.

LABEL IN PART: (Btl.) "Elixir Albephen Each 5 cc * * * contains Phenobarbital ¼ gr., Hyoscyamine Sulfate 0.104 mg., Atropine Sulfate 0.0195 mg., Hyoscine Hydrobromide 0.0065 mg., Alcohol 23%," "Merhistin Expectorant Each 30 cc * * * contains: Ephedrine Sulfate 40 mg., Citric Acid 3 gr., Merhistin Maleate 225 mg.," "Elixir Merbutal Each 5 cc * * * contains: * * * Sodium * * * Butyl barbiturate 3 grs.," and "Physicians Sample * * * Elixir Duophen Each 30 cc contains: Sodium pentobarbital 1 gr. * * * Phenobarbital 1 gr."

ACCOMPANYING LABELING: A number of loose labels for use in repacking the *elixir Albephen*, some of which were the same as the Albephen label described above and some of which read, in part, as follows: "Elixir Albephen Each Ounce contains: D. Amphetamine Sulfate 15 mg., Thiamin HCL 30 mg., Riboflavin 2.7 mg., Niacin 40 mg., Alcohol 10%."

RESULTS OF INVESTIGATION: The articles in the 1-pt. and 1-oz. btls. were repacked by the consignee from bulk stock which had been shipped as described above. The *elixir Albephen* and *elixir Merbutal* in the 1-gal. btls. represented

the bulk stock of those articles which had not been repacked as of the time of seizure.

LIBELED: 6–26–57, Dist. Md.

CHARGE: 501 (c)—the strength of the *elixir Merbutal*, while held for sale, differed from that which it was represented to possess, namely, 3 grains of butabarbital sodium per each 5 cc. (examination showed that the article contained about 80 percent less than the declared amount of butabarbital sodium); 502 (a)—the labeling of the *elixir Albephen*, while held for sale, namely, the labels intended for use in repacking the article, contained statements representing and suggesting that the article contained d. amphetamine sulfate, thiamine, riboflavin, and niacin, which statements were false and misleading since the article did not contain those ingredients; 502 (d)—the *elixir Merbutal*, while held for sale, contained a derivative of barbituric acid, and the label of the article, while held for sale, failed to bear in juxtaposition with the name and quantity of such derivative the statement "Warning—May be habit forming"; and 503 (b) (4)—the *elixir Albephen* (1-pt. btls.), *Merhistin expectorant*, and *elixir Duophen* were drugs subject to 503 (b) (1), and, while held for sale, their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The libel alleged also that another article, vitamin tablets, was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 7–24–57. Consent—claimed by Meredyth Co. The drugs were relabeled.

5402. Vitamin capsules. (F. D. C. No. 40238. S. No. 65–996 M.)

QUANTITY: 12 100-capsule btls., 21 50-capusle btls., and 13 30-capsule btls. at San Francisco, Calif.

SHIPPED: 11–13–56, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Bulk container) "NRC No. 2 Therapeutic Vitamin Formula Each Capsule Contains: Thiamin HCL 10 Mgm. Riboflavin 10 Mgm. Niacinamide 100 Mgm. Calcium Pantothenate 20 Mgm. Pyridoxine HCL 2 Mgm. Folic Acid 1.5 Mgm. Ascorbic Acid 300.0 Mgm. Vitamin K 2 Mgm. Vitamin B–12 * * * 4.0 Mcgm."

RESULTS OF INVESTIGATION: The article was shipped in a bulk container from Philadelphia, Pa., and upon arrival at San Francisco, Calif., was repacked and relabeled by the consignee.

Analysis showed that the article contained a significant amount of estrogenic hormone.

LIBELED: 5–6–57, N. Dist. Calif.

CHARGE: 501 (c)—the quality and purity of the article, when shipped, differed from that which it purported to possess; 501 (d) (2)—an estrogenic hormone had been substituted in part for vitamins; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use; and 503 (b) (4)—the article was a drug which was subject to 503 (b) (1) (B), and the label of the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 5–21–57. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5403. Mediatric (estrone) capsules, pentaerythritol tetranitrate tablets, and diphenmethanil methylsulfate tablets. (F. D. C. No. 40220. S. Nos. 62–528 M, 62–530/2 M.)

QUANTITY: 1 300-capsule btl. of *Mediatric (estrone) capsules*, 1 3,500-tablet btl. and 1 1,500-tablet btl. of *pentaerythritol tetranitrate tablets* and 1 250-tablet btl. of *diphenmethanil methylsulfate tablets* at New York, N. Y.

SHIPPED: On unknown dates, from Detroit, Mich., Cleveland, Ohio, and Morris Plains and Bloomfield, N. J.

LIBELED: 5–29–57, S. Dist. N. Y.

CHARGE: *Mediatric capsules.* 502 (b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502 (e) (2)—the label of the article failed to bear the common or usual name of each active ingredient; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

Pentaerythritol tetranitrate tablets. 503 (b) (4)—the article was a drug subject to 503 (b) (1); and, while held for sale, its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Diphenmethanil methylsulfate tablets. 502 (d)—the article contained a chemical derivative of barbituric acid (phenobarbital); and, while held for sale, the label failed to bear the quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: 7–16–57. Default—destruction.

5404. Botanical Medicine. (F. D. C. No. 39316. S. No. 27–771 M.)

QUANTITY: 302 16-oz. btls. and 67 32-oz. btls. at Tampa, Fla., in the possession of M. M. Moran.

SHIPPED: Between 3–29–56 and 9–29–56, from Cincinnati, Ohio.

LABEL IN PART: (Btl.) "Chief Whahoo Brand Botanical Medicine * * * Active Laxative Ingredients: Buckthorn, Senna, Cascara Sagrada and Aloe. Inactive Ingredients: Ginger, Calamus, Anise, Licorice, Mandrake, Methyl Salicylate, Salicylic and Benzoic Acid, Iron and Ammonium Citrate, Saccharin Soluble, Cassia and Spearmint Oil, Wahoo, Butternut, Uva Ursi, Sarsaparilla, Colocynth, Buchu, Juniper Berries and Wild Cherry."

ACCOMPANYING LABELING: Circulars designated "Your Digestive System."

RESULTS OF INVESTIGATION: The circulars were printed locally on order of the consignee and were used by the consignee, together with oral statements, to promote the sale of the article.

LIBELED: 8–6–56, S. Dist. Fla.; amended libel on or about 10–30–56.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for headache, dizziness, sour stomach, coated tongue, bad breath, skin eruptions, loss of appetite, indigestion, and sickness generally; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in purifying the blood and removing poisons from the liver, kidneys, bowels, stomach, and blood stream, which were the conditions and purposes for

*See also No. 5402.

which the article was intended and for which it was offered orally by the consignee to prospective purchasers.

DISPOSITION: 9–12–58. Default—destruction.

5405. Oza Compound. (F. D. C. No. 39849. S. No. 59–960 M.)

QUANTITY: 15 cases, 4 1-gal. jugs each, at Tampico, Ill.

SHIPPED: 11–28–56, from Fort Wayne, Ind., by Oza Compound Products.

LABEL IN PART: (Jug) "OZA * * * Formula: Active Ingredients: Alum, Oak Bark, Rosin, Sodium Benzoate Oza Compound * * * Use as a general tonic * * * Directions: Children, up to 5 years, 1 tablespoonful, 5 to 10 years, 2 tablespoonsful, 10 to 15 years, 3 tablespoonsful. Adults, 4 tablespoonsful, after each meal."

LIBELED: 1–29–57, N. Dist. Ill.

CHARGE: 502 (a)—when shipped, the label of the article bore the statement "Use as a general tonic," which statement was false and misleading since the article was not a tonic; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, and, because of its unscientific formula, it was not feasible to devise directions under which the layman could use the article to accomplish the purposes for which it was intended.

DISPOSITION: Willard Smith, t/a Oza Compound Products, appeared as claimant; and, on 3–15–57, upon stipulation of the parties, an order was entered directing that the case be transferred to the Southern District of Indiana. Interrogatories were served upon, and answered by, the claimant.

On 5–8–58, a consent decree of condemnation was entered; and, on 5–14–58, the article was ordered destroyed.

5406. Ovacide. (F. D. C. No. 40221. S. No. 66–334 M.)

QUANTITY: 17 6-oz. jars and 2 12-oz. jars and 1 drum containing 20 lbs. at Oakland, Calif.

SHIPPED: 2–22–56, from Portland, Oreg.

LABEL IN PART: (Jar) "Ovacide * * * Antiseptic Powder."

LIBELED: 5–24–57, N. Dist. Calif.

CHARGE: 502 (a)—while held for sale, the name "Ovacide" and certain statements on the jar label represented and suggested that the article was antiseptic under conditions of use and was an adequate and effective treatment for all vaginal infections and inflammed catarrhal conditions of the mucous membranes, which name and statements were false and misleading since the article was not antiseptic under conditions of use and was not an adequate and effective treatment for the conditions represented; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use since the directions failed to specify that the article should not be used more than twice weekly for cleansing purposes only, unless otherwise directed by a physician.

DISPOSITION: 6–11–57. Default—destruction.

5407. Head harness device. (F. D. C. No. 40214. S. No. 72–962 M.)

QUANTITY: 15 devices at Salt Lake City, Utah.

SHIPPED: 3–27–57, from Idaho Falls, Idaho, by Clifford Thiede.

LABEL IN PART: "Thiede's Stretch-To-Health Head Harness Spine Normalizer Patent Applied For Serial No. D–27615 Manufactured and designed by Cliff Thiede 250 Shelley Street Phone 4293 Idaho Falls, Idaho."

ACCOMPANYING LABELING: Pamphlets entitled "Well I'll Be Hanged! Stretch Your Spine For Health."

RESULTS OF INVESTIGATION: The device consisted of chains, a doorway hanger, and a head harness for suspending the head.

LIBELED: 6–12–57, Dist. Utah.

CHARGE: 502 (a)—when shipped, the designation "Thiede's Stretch-To-Health Head Harness" and the labeling of the devices contained false and misleading representations that the devices were an adequate and effective treatment for normalizing the spine muscles, spasm, osteoarthritis, disc degeneration, herniated disc or disc protrusion, neuritis, headaches (migraine), nervous disorders, premature aging, poor circulation, poor elimination of waste material, decreased body functions, chronic strain, thinning of the vertebral discs, back and neck troubles, serious injury and malfunctioning of the organs of the body, and promoting and maintaining health; and 502 (f) (1)—the devices should be restricted to sale only on prescription since they were devices, which because of any potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, were not safe except under the supervision of a practitioner licensed by law to direct the use of such devices, and hence for which "adequate directions for use" could not be prepared; and their labels failed to bear the statement "Caution: Federal law restricts this device to sale by or on the order of a ————, (the blank to be filled in by the professional designation of a properly licensed member of a professional group)."

DISPOSITION: 8–23–57. Consent—claimed by Clifford Thiede and relabeled.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5408. Digitoxin powder and digitoxin tablets. (F. D. C. No. 40157. S. Nos. 60–319/20 M.)

QUANTITY: 1 25-gram btl. of *digitoxin powder* and 69 1,000-tablet btls. of *digitoxin tablets* at Detroit, Mich.

SHIPPED: 11–27–56, from New York, N. Y., by European Chemical Co., Inc.

LABEL IN PART: (Btl.) "Digitoxin U. S. P. For Manufacturing Use Only * * * Net 25 gms. European Chemical Co., Inc., New York, N. Y." and "Digitoxin, Mallard, 1000 tablets, White Round * * * Mallard, Inc., Detroit, Mich."

RESULTS OF INVESTIGATION: The *digitoxin tablets* were prepared by the consignee using a portion of the bulk *digitoxin powder*.

Examination showed that the powder contained not more than 83.5 percent of digitoxin and that the tablets contained not more than 0.162 milligrams of digitoxin per tablet.

LIBELED: 4–23–57, E. Dist. Mich.

CHARGE: 501 (b)—the *digitoxin powder* and the *digitoxin tablets* purported to be a drug, "Digitoxin," the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when the powder was shipped and while the tablets were held for sale, the strength of the articles differed

*See also Nos. 5401, 5402.

from, and their quality fell below, the official standard since the articles contained less than 90 percent of the labeled amount of digitoxin, the minimum permitted by the standard.

DISPOSITION: 6–25–57. Default—destruction.

5409. Digitoxin powder and digitoxin tablets. (F. D. C. No. 40117. S. Nos. 42–964/5 M.)

QUANTITY: 1 24-gram btl., 14 1,000-tablet btls., and 4 100-tablet btls. at Peoria, Ill.

SHIPPED: Between 12–1–55 and 1–18–57, from Newark, N. J., by Chemo Puro Mfg. Corp.

LABEL IN PART: (Btl.) "Digitoxin U. S. P. * * * For Manufacturing, Processing or Repacking" and "Digitoxin Tablets Each tablet contains Digitoxin. . . . 0.22 mg. (1/300 gr.)."

RESULTS OF INVESTIGATION: The above tablets were prepared by the consignee from the bulk powder shipped on or about 12–1–55.

Examination showed that the powder contained not more than 85.8 percent of digitoxin and that the tablets contained not more than 70.2 percent of digitoxin when assayed by the methods specified in the United States Pharmacopeia. The Pharmacopeia requires that the assay result be not less than 90 percent of digitoxin.

LIBELED: 4–4–57, S. Dist. Ill.

CHARGE: 501 (b)—the article, when shipped and while held for sale, purported to be a drug, "Digitoxin," the name of which is recognized in the United States Pharmacopeia, an official compendium, and the strength of the article differed from, and its quality fell below, the standard set forth in such compendium.

DISPOSITION: 5–13–57. Default—destruction.

5410. Digitoxin tablets. (F. D. C. No. 40173. S. Nos. 62–829/31 M.)

QUANTITY: 75,600 tablets packed in btls. of 100, 500, and 1,000 tablets; 154,100 tablets in a fiber drum and in bottles; and 97,000 tablets in a fiber drum, at Brooklyn, N. Y.

SHIPPED: On or about 5–4–55, from Paris, France.

LABEL IN PART: (Drum) "Digitoxin 0.1 mg. [or "0.2 mg."]"; (btl.) "Digitoxin Tablets U. S. P. 0.1 mg. [or "0.2 mg."]."

RESULTS OF INVESTIGATION: A quantity of digitoxin powder was shipped as described above; and, upon arrival at Brooklyn, N. Y., it was used to prepare the *digitoxin tablets.*

Examination showed that the tablets contained digitoxin in amounts of not more than (75,600-tablet lot) 82.4 percent of the declared amount, (154,100-tablet lot) 84.2 percent of the declared amount, and (97,000-tablet lot) 76.2 percent of the declared amount.

LIBELED: 5–1–57, E. Dist. N. Y.

CHARGE: 501 (b)—while held for sale, the strength of the article differed from, and its quality fell below, the standard for digitoxin set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin.

DISPOSITION: 6–4–57. Default—destruction.

5411. Digitoxin tablets. (F. D. C. No. 40174. S. No. 55–353 M.)

QUANTITY: 1 drum containing 99,800 tablets at Indianapolis, Ind.

SHIPPED: 1–30–57, from St. Louis, Mo., by Private Formulae, Inc.

LABEL IN PART: "Tablets 0.1 Mg. Digitoxin."

RESULTS OF INVESTIGATION: Examination showed that the tablets contained not more than 74.7 percent of the declared amount of digitoxin.

LIBELED: 5–10–57, S. Dist. Ind.

CHARGE: 501 (b)—the strength of the article, when shipped, differed from the standard for digitoxin tablets set forth in the United States Pharmacopeia, an official compendium, since the article contained less than 90 percent of the labeled amount of digitoxin when assayed by the method specified in the compendium.

DISPOSITION: 7–16–57. Default—destruction.

5412. Hydrogen peroxide. (F. D. C. No. 40094. S. No. 24–038 M.)

QUANTITY: 7 cases, 12 4-oz. btls. ea., at Phoenix, Ariz.

SHIPPED: Between 1–15–57 and 1–24–57, from Los Angeles, Calif., by Norton Products Co.

LABEL IN PART: (Btl.) "Enterprise * * * Solution of Hydrogen Peroxide U. S. P. 10 volume * * * Active Ingredient Hydrogen Peroxide 3% Inert Ingredient 97% * * * Enterprise Drug & Chemical Co., Los Angeles, Calif."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 5.0 percent isopropyl alcohol, an ingredient which is not permitted by the standard in the United States Pharmacopeia for hydrogen peroxide solution.

LIBELED: 3–19–57, Dist. Ariz.

CHARGE: 501 (b)—the article, when shipped, purported to be and was represented as a drug, "Hydrogen Peroxide Solution," the name of which is recognized in the United States Pharmacopeia, an official compendium, and the purity and quality of the article fell below the standard set forth in such compendium.

DISPOSITION: 5–31–57. Default—destruction.

5413. Menadione sodium bisulfite. (F. D. C. No. 40209. S. No. 59–377 M.)

QUANTITY: 4 ampuls at Philadelphia, Pa.

SHIPPED: 2–19–57, from New York, N. Y., by Delta Chemical Works.

RESULTS OF INVESTIGATION: Analysis showed that the article contained 74.6 percent of menadione sodium bisulfite.

LIBELED: 5–15–57, E. Dist. Pa.

CHARGE: 501 (b)—the article purported to be and was represented as "Menadione Sodium Bisulfite," a drug the name of which is recognized in the United States Pharmacopeia, and the strength of the article, when shipped, differed from the standard set forth in the United States Pharmacopeia since the article contained less than 94 percent of the labeled amount of menadione sodium bisulfite; and 502 (a)—the label statement "22 g. Menadione Sodium Bisulfite" was false and misleading.

DISPOSITION: 6–17–57. Default—destruction.

5414. Vitamin capsules. (F. D. C. No. 40183. S. No. 45–504 M.)

QUANTITY: 598 btls., 100 capsules ea., at Richmond, Va.

SHIPPED: 12–9–52, from Detroit, Mich.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the declared amount of vitamin D and vitamin B_1.

LIBELED: 4–26–57, E. Dist. Va.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it was represented to possess, namely, 1,200 U. S. P. units of vitamin D and 10 mg. of vitamin B_1; and 502 (a)—the label statements "Vitamin D—1200 U. S. P. units" and "Vitamin B_1—10 mg." were false and misleading.

DISPOSITION: 6–3–57. Default—destruction.

5415. Clinical thermometers (rectal). (F. D. C. No. 41419. S. No. 15–168 P.)

QUANTITY: 114 *clinical thermometers* at Youngstown, Ohio.

SHIPPED: 6–28–57, from Ridgewood, N. Y., by Comet Thermometer Co.

RESULTS OF INVESTIGATION: Examination of 24 *clinical thermometers* showed that 17 failed to meet the requirement for accuracy specified in CS1–52 issued by the National Bureau of Standards of the Department of Commerce when tested as described in CS1–52.

LIBELED: 2–11–58, N. Dist. Ohio.

CHARGE: 501 (c)—when shipped, the quality of the article fell below that which it purported and was represented to possess since it did not give accurate readings; and 502 (a)—the label statement "tested and found to meet all the requirements and tests specified in Commercial Standard CS1–52" was false and misleading.

DISPOSITION: 3–25–58. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

5416. Ante-Firmin. (F. D. C. No. 40216. S. Nos. 39–439/40 M.)

QUANTITY: 22 ctns., ea. containing 12 2-oz. btls., at Charlotte, N. C.

SHIPPED: 11–26–56 and 4–18–57, from Clinton, S. C., by Ante-Firmin Co.

LABEL IN PART: "Ante-Firmin * * * Children's Prescription * * * Alcohol 4% Represents Rhubarb, Bismuth Subnitrate, Calcium Carbonate, Zinc Phenol Sulfonate, Cinnamon, Oil of Peppermint" and "Ante-Firmin * * * Adult Prescription * * * Alcohol 6 percent Represents Rhubarb, Bismuth Subnitrate, Calcium Carbonate, Zinc Phenolsulfonate, Tinct Capsicum, Cinnamon, Oil of Peppermint."

LIBELED: 5–20–57, W. Dist. N. C.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was effective as a laxative and antacid for the treatment of stomach acidity, stomach distress, and simple diarrhea.

DISPOSITION: 6–19–57. Default—destruction.

5417. Snodgrass Mixture. (F. D. C. No. 40296. S. No. 64–189 M.)

QUANTITY: 11 cartons, 12 btls. ea., at Pittsburgh, Pa.

SHIPPED: 2–18–57, from Kenmore, N. Y., by Barworth Distributing Corp.

*See also Nos. 5401, 5404–5407, 5413–5415.

LABEL IN PART: "Snodgrass Mixture * * * Contains solution of Bismuth & Ammonium Citrate. ⅛ min. Carbolic Acid to the teaspoonful."

ACCOMPANYING LABELING: Display cards reading in part "Ulcer Sufferers * Authorized Dealer * Snodgrass Mixture—For relief of stomach hyperacidity."

RESULTS OF INVESTIGATION: Analysis showed that the article contained in one teaspoonful (5 milliliters) 0.315 gram of bismuth and ammonium citrate and 7.6 milligrams of phenol.

LIBELED: 6–3–57, W. Dist. Pa.

CHARGE: 502 (a)—the labeling which accompanied the article, when shipped, contained false and misleading representations that the article was an effective treatment for ulcers.

DISPOSITION: 8–6–57. Default—destruction.

5418. Quaff-Aid tablets. (F. D. C. No. 39645. S. No. 48–861 M.)

QUANTITY: 117,000 tablets in 2 bulk drums and 140,000 tablets in small cellophane envelopes containing 2 tablets ea. at Milwaukee, Wis., in possession of Amber Laboratories, Inc.

SHIPPED: 8–4–55, from Chicago, Ill.

LABEL IN PART: (Envelope) "Quaff-Aid * * * Ingredients: Specially Prepared Concentrated Brewers' Yeast."

RESULTS OF INVESTIGATION: The article in the above-described shipment was purchased in bulk drums; and, after its receipt at Milwaukee, Wis., it was in part repackaged into envelopes for retail sale by the dealer.

LIBELED: 10–23–56, E. Dist. Wis.

CHARGE: 502 (a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for preventing and relieving all ill effects from overindulgence in alcohol.

DISPOSITION: 4–15–57. Consent—claimed by Amber Laboratories, Inc., and relabeled.

5419. Honey. (F. D. C. No. 40333. S. No. 61–325 M.)

QUANTITY: 2 cases, each containing 24 jars, labeled as described below, and 208 cases, each containing 24 1-lb. unlabeled jars, at Dorchester, Mass., in the possession of George P. Margeson.

SHIPPED: Between 5–3–57 and 6–4–57, from Kew Gardens, N. Y.

LABEL IN PART: (Jar) "Margeson's Nutritious Honey * * * From Guatemala, Central America ROSE Brand Net Wt. 1 lb. Imported and Packed For Geo. P. Margeson Boston Mass."

ACCOMPANYING LABELING: Circulars entitled "My Son Eat Thou Honey, For it is Good" and "Guatemala Rose Honey and I."

RESULTS OF INVESTIGATION: The unlabeled jars of the article were to be labeled with the same label that appeared on the labeled jars. The above-mentioned circulars were printed locally for the consignee.

LIBELED: 6–21–57, Dist. Mass.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was effective for overcoming heart conditions and kidney conditions, preventing colds,

providing health, improving strength, acting as a laxative, and for acting as specific nutrition to the heart for preventing heart fatigue.

DISPOSITION: 9–3–58. Consent—claimed by George P. Margeson and released for relabeling.

DRUGS FOR VETERINARY USE

5420. Veterinary drugs. (F. D. C. No. 40292. S. Nos. 39–181/3 M.)

QUANTITY: 10 1-gal. jugs and 84 2-oz. btls. and 540 1-oz. btls. of *Red Head Pox Remedy* and 36 2-oz. btls. and 8 1-oz. btls. of *Red Head Cocci Nox* at Orlando, Fla., in possession of Blue Ball Chemical Co.

SHIPPED: On 8–10–56, a 20-gal. bbl. of tincture of aconite was shipped from Lyndhurst, N. J.

LABEL IN PART: (Jug) "Red Head Pox Remedy"; (btls.) "Red Head Cocci Nox * * * Active Ingredients Tincture Aconite 100%" and "Red Head Pox Remedy * * * Active Ingredients: Aconite . . . 15% Alcohol . . . 65.00% Inert Ingredients . . . 34.85% Total . . . 100%."

RESULTS OF INVESTIGATION: A quantity of the tincture of aconite, after its shipment as described above, was repacked and relabeled by the consignee into the above-mentioned jugs and bottles.

LIBELED: On or about 6–4–57, S. Dist. Fla.

CHARGE: 502 (a)—while held for sale, the labels of the articles contained false and misleading representations that the *Red Head Pox Remedy* was an effective treatment for fowlpox and that the *Red Head Cocci Nox* was an effective treatment for intestinal coccidiosis and for drooping, poor feeding, inactive birds.

DISPOSITION: 8–2–57. Default—destruction.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U. S. GOVERNMENT PRINTING OFFICE: 1959

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5421–5440

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503 (b) (1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C. *April 6, 1959.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

5421. (F.D.C. No. 39977. S. Nos. 34–658 M, 34–663 M, 34–671 M, 34–675 M.)

INFORMATION FILED: 5–9–57, S. Dist. Ind., against **Louis F. Wolf (pharmacist for Oakley Drug Store), Terre Haute, Ind.**

CHARGE: Between 2–21–56 and 3–15–56, *Benzedrine Sulfate Spansule capsules* and *pentobarbital sodium capsules* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 6–27–57. $2,000 fine, plus costs.

5422. (F.D.C. No. 40466. S. Nos. 56–151 M, 56–153 M, 56–157 M, 71–919 M.)

INFORMATION FILED: 11–26–57, N. Dist. Ill., against **Lawndale Drug Co. (a partnership), Chicago, Ill., and Irving Feldman and Barney Goldberg (partners).**

CHARGE: Between 1–21–57 and 4–11–57, *Dexedrine Sulfate capsules* (counts 1 and 2) and *Butisol Sodium tablets* (counts 3 and 4) were each dispensed twice without a prescription.

PLEA: Guilty by partnership to all 4 counts of information, by Feldman to counts 1, 3, and 4, and by Goldberg to count 2.

DISPOSITION: 12–16–57. Fine of $200, plus costs, against partnership, $450 against Feldman, and $100 against Goldberg.

5423. (F.D.C. No. 39848. S. Nos. 45–088/93 M, 45–102/3 M.)

INFORMATION FILED: 8–21–57, Dist. Md., against **Jerome Richmond, t/a Capitol Drug Store, Baltimore, Md., and Vincent J. Piraino (pharmacist).**

CHARGE: Between 7–31–56 and 8–31–56, *Dexedrine Sulfate tablets*, which had been shipped in interstate commerce into the State of Maryland (counts 1, 2, and 3), and *pentobarbital sodium capsules*, which had been fabricated in the State of Maryland from pentobarbital sodium powder that had been shipped in interstate commerce (counts 4, 5, and 6), were each dispensed 3 times upon requests for prescription refills without authorization by the prescriber; and *crystalline procaine penicillin troches* (count 7) and *buffered penicillin tablets* (count 8), which had been shipped in interstate commerce into the State of Maryland, were each dispensed once without a prescription.

PLEA: Guilty by Richmond to all counts of information and by Piraino to counts 1, 2, 4, 5, and 8.

DISPOSITION: 9–27–57. Richmond fined $1,000, plus costs, and Piraino fined $100, plus costs. Each defendant placed on probation for 5 years.

5424. (F.D.C. No. 39973. S. Nos. 40–479 M, 40–588/9 M.)

INFORMATION FILED: 4–1–57, W. Dist. Wis., against **Oliver P. Mueller, t/a Mueller Drugs, Prairie du Sac, Wis.**

CHARGE: Between 6–21–56 and 8–14–56, *Dexedrine Spansule capsules* were dispensed once without a prescription and twice upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 4–9–57. $150 fine.

5425. (F.D.C. No. 39963. S. Nos. 22–898 M, 49–557 M, 49–632 M, 49–640 M, 49–668 M, 49–670/1 M, 49–816 M.)

INFORMATION FILED: 6–5–57, Dist. Mass., against **Edward L. Doolan, t/a Raleigh Drug Co., Springfield, Mass., and Robert J. O'Neil (pharmacist).**

CHARGE: Between 5–8–56 and 6–14–56, *Dexedrine Spansule capsules* (counts 1 and 7), *Gantrisin tablets* (counts 2 and 5), *secobarbital sodium capsules* (counts 3 and 6), and *Butazolidin tablets* (counts 4 and 8) were each dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by Doolan to all counts of information and by O'Neil to counts 1, 3, 4, 5, and 8.

DISPOSITION: 10–7–57. Doolan fined $1,000 and O'Neil $200.

5426. (F.D.C. No. 40442. S. Nos. 62–462 M, 62–465 M, 62–480 M, 63–293 M.)

INFORMATION FILED: 10–3–57, E. Dist. N. Y., against **Pincus Goldman, Brooklyn, N.Y.**

CHARGE: Between 2–5–57 and 3–7–57, *Gantrisin tablets* and *Dexedrine Sulfate tablets* were each dispensed once upon request for prescription refills without authorization by the prescriber, and *AM Plus capsules* and *Banthine tablets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–5–57. $400 fine.

5427. (F.D.C. No. 40425. S. Nos. 43–447/8 M, 44–526/7 M.)

INFORMATION FILED: 7–5–57, W. Dist. Ky., against **Herschel G. Compton, t/a Rogers Rexall Drug Store, Barlow, Ky.**

CHARGE: Between 3–22–57 and 3–29–57, *thyroid tablets*, *Dexedrine Sulfate tablets*, *Equanil tablets*, and *secobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–29–57. $200 fine.

5428. (F.D.C. No. 35147. S. Nos. 2–527 L, 2–530 L, 2–548 L, 59–621 L, 59–624/5 L.)

INFORMATION FILED: 1–6–54, S. Dist. Fla., against **Rutherford T. Carlisle, t/a Carlisle Drugs, Jacksonville, Fla.**

CHARGE: Between 12–8–52 and 2–16–53, *dextro-amphetamine sulfate tablets* were dispensed twice (counts 1 and 2) and *thyroid tablets* were dispensed once (count 3) without a prescription, and *secobarbital sodium capsules* were dispensed twice (counts 4 and 5) and *pentobarbital sodium capsules* were dispensed once (count 6) upon request for a prescription refill without authorization by the prescriber.

DISPOSITION: On 1–27–54, the defendant entered a plea of not guilty. Thereafter, he filed a motion for discovery and inspection, a motion for return of seized property and suppression of evidence, a motion for bill of particulars, and a motion to dismiss. On 8–4–55, the court denied the motion for return of seized property and suppression of evidence; granted the motion for discovery, in part; granted the motion for bill of particulars, in part; and denied the motion to dismiss as to counts 1 through 3, and granted the motion to dismiss as to counts 4, 5, and 6, thereby dismissing those counts.

The defendant filed a motion for rehearing; and the Government filed a motion for rehearing and a motion for order clarifying the basis for the

dismissal of counts 4, 5, and 6. On 9–2–55, the court denied all three motions.

The Government appealed the dismissal of counts 4, 5, and 6 to the United States Court of Appeals for the Fifth Circuit. On 5–31–56, the court of appeals handed down the following opinion (234 F. 2d. 196):

HUTCHESON, *Chief Judge:* "The appeal is taken pursuant to 18 U.S.C. 3731, from a final order dismissing Counts IV,[1] V and VI of a six count criminal information instituted under the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.

"Each of the three counts involved charges a separate violation of 21 U.S.C. 331(k). Each count charges that on different occasions the defendant caused an act to be done with respect to a drug while it was being held for sale after shipment in interstate commerce, in effect refilling a prescription without the authorization of its prescriber, as required by 21 U.S.C. Sec. 353(b)(1), which resulted in the drugs being misbranded.

"In Count IV there is involved the drug secobarbital sodium or seconal, and in Counts V and VI the drug sodium pentobarbital. The information alleges both of these drugs to be within the class of drugs described in 21 U.S.C. 353(b)(1)(A), i.e., a habit-forming drug to which 21 U.S.C. 352(d) applies.

"The defendant moved to dismiss the information citing thirteen grounds therefor, including alleged defects in both the information and the statute.

"On August 4, 1955, the district court denying defendant's motion as to Counts I, II, and III, granted it as to, and ordered dismissal of, Counts IV, V, and VI.

"Appealing from the order of dismissal, the United States is here insisting that each of the dismissed counts states facts sufficiently charging an offense in that each count specifically and clearly charges that the act of dispensing

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[1] "COUNT IV—

"The United States Attorney further charges:

"That prior to Feb. 16, 1953, a number of secobarbital sodium capsules, a drug within the meaning of 21 U.S.C. 353(b)(1)(A) as amended, were shipped in interstate commerce into the State of Florida, in a bottle labeled in part as follows:

Caution—Federal law prohibits
dispensing without prescription.

"That thereafter, on or about Feb. 16, 1953, and while a number of capsules of said drug were being held for sale after shipment in interstate commerce, as aforesaid, at Carlisle Drugs, 5012 West Beaver Street, Jacksonville, Florida, the said Rutherford T. Carlisle, an individual, at the times hereinbefore mentioned trading and doing business as Carlisle Drugs, the defendant herein, did, at Jacksonville, Florida, within the Southern District of Florida, cause a number of capsules of said drug to be dispensed in a vial to one Hosea R. Wallace, upon his request for a refill of a written prescription identified as number 8683, issued on or about Feb. 11, 1953, without obtaining authorization by the prescriber;

"That displayed upon said vial was certain labeling which consisted among other things, of the following printed and graphic matter:

Carlisle Drugs
5012 W. Beaver St. Jacksonville, Florida
No. 8683 Dr. Grizzard
George R. Fowler
One only at bed time
2.13.53

"That said act of causing the dispensing of said drug as aforesaid was an act caused to be done by said defendant, contrary to the provisions of 21 U.S.C. 353(b)(1), which resulted in said drug in said vial being misbranded while held for sale, in violation of Title 21, U.S. Code, Sec. 331(k)."

Count V is identical with Count IV except as to the drug, the person to whom dispensed and the date of dispensing, while Count VI is identical with Count V except as to the date of dispensing.

as alleged was prohibited by 21 U.S.C. 353(b)(1),[2] and in violation of 21 U.S.C. 331(k),[3] for which sec. 333,[4] 21 U.S.C. prescribes the penalty.

"In support of this position, it points out that the last sentence of 21 U.S.C., 353(b)(1), recited in each of the dismissed counts, provides that the act of dispensing a drug contrary to the provisions of this paragraph *'shall be deemed to be an act which results in the drug being misbranded while held for sale,'* [*Emphasis supplied*], an act prohibited by Sec. 331(k) which prohibits 'the alteration, mutilation * * * *or the doing of any other act with respect to a food, drug* * * * *while such article is held for sale* (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.' [*Emphasis supplied.*]

"Appellee agrees that Counts IV, V, and VI charge the appellee with refilling a written prescription without obtaining the authorization of the prescriber, that each count charges that the barbiturate in question is a drug within the meaning of 21 U.S.C. 353(b)(1) and that each count then goes on to allege that the act of dispensing the drug was an act done by the appellee contrary to the provisions of 21 U.S.C. 353(b)(1), 'which resulted in said drug in said box being misbranded while held for sale in violation of 21 U.S.C. 331(k).'

"He argues that each of the counts are duplicitious in that they charge two offenses, (1) dispensing drugs without a prescription and (2) that the drug was misbranded in violation of another section.

"In addition, without clearly pointing out why that would make them so, appellee insists that Sections 353(b)(1) and 331(k) are unconstitutional in that they purport to affix a meaning and give a content to the word, 'misbranded' quite the contrary to the meaning given it in Webster's Dictionary and the federal cases, to-wit: 'to brand falsely; specifically, to brand as containers of drugs or food stuffs in contravention of statutory requirements.' So insisting and citing in support *U.S.* v. *Cargill*, 334 U.S. 174, and *Connally* v. *General Construction*, 269 U.S. 385, appellee urges upon us that the sales of the barbiturates did not and could not amount to 'alteration, mutilation, destruction, obliteration, or removal of the whole or any part of labelling;' as defined in Sec. 331(k); that the appellant must, therefore, contend that the offense is charged in that part of the section which provides, 'or the doing of any other act with respect to food, drugs, * * * which results in such article being adulterated or misbranded,' and that this produces a contradiction and vagueness which deprives the defendant of due process in failing to give him notice of the offense with which he is charged.

"We do not regard these positions as well taken. Giving the fullest effect possible to appellee's objections, they come at last to no more than this, that it is an unduly awkward way to go about charging an offense to have to rely upon three separated sections to make it out. While at first blush this seems to be so, upon analysis and understanding it clearly enough appears: that, as to drugs of the habit forming group, congress has prohibited the refilling of a prescription therefor without authorization of the issuing physi-

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[2] 21 U.S.C. 353(b)(1)

"A drug intended for use by man which—

(A) is a habit-forming drug to which section 352(d) applies; or

* * * * * * *

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filled by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale."

[3] 21 U.S.C. 331(k)

"The following acts and the causing thereof are hereby prohibited:

* * * * * * *

"(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

[4] 21 U.S.C. 333. Penalties—Violation of Sec. 331.

"(a) Any person who violates any of the provisions of Sec. 331 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1000, or both such imprisonment and fine; * * *."

cian; and that, instead of fixing the penalty for this act by directly setting it out in the section carrying the prohibition, it has declared the act of so refilling to be the same as misbranding and subject to the same penalty.

"It did this by setting out in 353(b)(1) the only way in which drugs of the kind dealt with can be dispensed, and then in the same section going on to say that the act of dispensing such a drug, contrary to the provisions of the paragraph, shall be deemed to be an act which results in the drug being misbranded. This established, by law in this section, there is required only resort to 21 U.S.C. 331(k), which denounces the offense of misbranding, and to Sec. 333, which fixes the penalty for that offense. When this resort is had, the conclusion is inescapable, we think, that the sections taken together have provided as clearly as though it had all been written out in the same section, that one dispensing drugs of the kind dealt with here, contrary to the provisions of Sec. 353(b)(1) shall be guilty of, and subject to the punishment provided by law for, an act of misbranding.[5] This necessarily results from the use in Sec. 353(b)(1) of the language, 'the act shall be deemed to be an act which results in the drug being misbranded while held for sale.'

"In *Bowers* v. *United States*, 226 F.(2) 424, this court dealt with a statute using substantially the same language. We there pointed out, one judge dissenting, that a statute using the words 'deemed to have been marketed in excess of the quota' was intended to operate not as a presumption of fact but as a statement of a substantive rule of law, the meaning, purpose and effect of which was that the same penalty should be imposed for the failure of the producer to account for the disposition of any peanuts as was provided for, and imposed upon, excess marketing. As we held there, we hold here, that the use of the word 'deemed' in the act creates an irrebuttable presumption, a rule of substantive law, and that the doing of the prohibited act, dispensing the drugs contrary to the provision of Sec. 353(b)(1) and without the authorization of the prescriber, makes refilling misbranding and subjects the dispenser to the penalties provided for misbranding.

"It was error to dismiss the three counts. The order is REVERSED and the cause is REMANDED for further and not inconsistent proceedings.

"CAMERON, *Circuit Judge:* 'I concur in the result.'"

The defendant petitioned for rehearing, which was denied on 6–30–56. A petition for a writ of certiorari was filed with the United States Supreme Court by the defendant; the court denied the petition (352 U.S. 841).

On 4–15–57, the defendant entered a plea of guilty to counts 4, 5, and 6 of the information, and the charges on counts 1, 2, and 3 were dismissed by the Government. On 4–26–57, the court fined the defendant $100.

5429. (F.D.C. No. 39191. S. Nos. 58–810/12 M.)

INFORMATION FILED: 6–15–56, Dist. Colo., against **Edith Lillian Every, also known as Mrs. H. R. Marshall, Denver, Colo.**

CHARGE: Between 5–18–56 and 5–31–56, *dextro-amphetamine sulfate tablets* were dispensed twice (counts 1 and 3) and *pentobarbital sodium capsules* were dispensed once (count 2) without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial on 10–15–56. On 10–16–56, the court dismissed counts 1 and 3 on the basis that the evidence presented by the Government was insufficient to establish that dextro-amphetamine sulfate is a drug within the meaning of Section 503(b)(1)(B). On 10–17–56, the jury found the defendant guilty as to count 2.

The defendant, on 11–2–56, made a motion for acquittal and a motion for a new trial, based upon the contention that a photostatic copy of a letter that had been introduced into evidence at the trial was (a) not the best evidence,

[5] United States v. Debrow, 346 U.S., 374; United States v. Sullivan, 332 U.S. 689; United States v. Arnold's Pharmacy, 116 Fed. Supp. 370; Jordan v. DeGeorge, 341 U.S. 223; Boyce Motor Lines v. United States, 342 U.S. 337.

as it was a photostatic copy and (b) obtained by unlawful search and seizure, and thus violated the defendant's constitutional rights. The court denied the motion for acquittal, stating that the other evidence produced by the Government was sufficient to refer the case to the jury. The court granted the motion for a new trial on the basis that the letter had been obtained by unlawful search and seizure and that the court had made an error in admitting the letter into evidence.

On 11–28–56, a new trial was held as to count 2, and the jury returned a verdict of guilty. On 11–30–56, the defendant was sentenced to 60 days in jail.

5430. (F.D.C. No. 40439. S. Nos. 36–320 M, 48–485/91 M.)

INFORMATION FILED: 11–27–57, N. Dist. Ill., against **Harold S. Goodman, t/a Janz Drugs, Chicago, Ill., and Frank S. LaCoy (apprentice pharmacist).**

CHARGE: Between 12–4–56 and 1–24–57, *dextro-amphetamine sulfate capsules* were dispensed 3 times, *secobarbital sodium capsules* were dispensed twice, and *Metandren Linguets, Candicillin* (brand of penicillin and bacitracin) *troches,* and *Pentids* (brand of penicillin G potassium) *tablets* were each dispensed once, without a prescription.

PLEA: Guilty by Goodman to all 8 counts of information and by LaCoy to counts 1, 2, 7, and 8 relating to dispensing of *dextro-amphetamine sulfate capsules, Metandren Linguets,* and *secobarbital sodium capsules.*

DISPOSITION: 12–16–57. Goodman fined $400, plus costs, and LaCoy fined $200.

5431. (F.D.C. No. 40432. S. Nos. 60–145 M, 72–350/2 M.)

INFORMATION FILED: 8–23–57, E. Dist. Mich., against **Ralph B. Carpenter, t/a Carpenter's Pharmacy, Royal Oak, Mich.**

CHARGE: Between 1–16–57 and 4–8–57, *dextro-amphetamine sulfate capsules* were dispensed three times and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–27–57. Defendant placed on probation for 2 years.

5432. (F.D.C. No. 39971. S. Nos. 40–902 M, 40–906 M.)

INFORMATION FILED: 2–28–57, Dist. Minn., against **Harry M. Zipperman, t/a Zipp's Pharmacy, Minneapolis, Minn., and Ashley H. Morse (pharmacist).**

CHARGE: Between 7–6–56 and 7–19–56, *dextro-amphetamine sulfate tablets* and *amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–25–58. Zipperman fined $750 and Morse $250. Each defendant placed on probation for 3 years.

5433. (F.D.C. No. 40451. S. Nos. 72–358 M.)

INFORMATION FILED: 11–4–57, E. Dist. Mich., against **Richard T. Furtney, t/a Furtney's Drug Store, Pontiac, Mich.**

CHARGE: On 4–9–57, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1–7–58. $500 fine.

5434. (F.D.C. No. 40456. S. Nos. 39–572 M, 77–568 M.)

INFORMATION FILED: 12–10–57, N. Dist. Fla., against **Marcus E. Williams, Pensacola, Fla.**

CHARGE: Between 4–27–57 and 7–11–57, *amphetamine sulfate tablets* were dispensed once at Pensacola, Fla., and *dextro-amphetamine sulfate tablets* were dispensed once at Tallahassee, Fla., without a prescription.

PLEA: Guilty.

DISPOSITION: 1–10–58. Sentence of 1 year in jail.

5435. (F.D.C. No. 39206. S. Nos. 27–423/30 M, 27–434 M, 53–802/9 M.)

INDICTMENT RETURNED: 8–2–57, N. Dist. Tex., against **Robert C. Magee (medical doctor), Dallas, Tex.**

CHARGE: Between 5–27–56 and 7–23–57, *amphetamine sulfate tablets* were dispensed 16 times without a prescription.

PLEA: Not guilty.

DISPOSITION: On 9–16–57, the defendant filed a motion to dismiss and a motion to strike, which were denied, and a motion for a bill of particulars, which was granted.

The case came on for trial before the court and jury on 9–18–57, and was terminated on 9–20–57, with the return by the jury of a verdict of not guilty.

5436. (F.D.C. No. 40139. S. Nos. 56–229/32 M.)

INFORMATION FILED: 7–11–57, N. Dist. Ill., against **Zeitkin's Pharmacy, Inc., Chicago, Ill., Albert Cotler (vice president and treasurer) and Stanley L. Lisowski (assistant pharmacist).**

CHARGE: Between 4–28–56 and 7–9–56, *Achromycin tablets* (counts 1 and 2) were dispensed twice and *Savatan capsules* (count 3) and *thyroid tablets* (count 4) were each dispensed once, without a prescription.

PLEA: Nolo contendere by corporation to all 4 counts of information, by Lisowski to counts 1, 2, and 4, and by Cotler to count 3.

DISPOSITION: 8–5–57. Corporation fined $300, plus costs; Lisowski, $150; and Cotler, $100.

5437. (F.D.C. No. 39841. S. Nos. 47–039 M, 47–042/3 M, 47–060 M.)

INFORMATION FILED: 5–31–57, Dist. N.J., against **David J. Barnett, t/a Bear Drug Co., Lambertville, N.J.**

CHARGE: Between 7–25–56 and 10–4–56, *Achromycin tablets* were dispensed twice and *Thorazine tablets* and *capsules containing a mixture of ergot, aloin, apiol, oil pennyroyal, and cottonseed oil* were each dispensed once, without a prescription.

PLEA: Guilty.

DISPOSITION: 7–15–57. $250 fine and probation for 1 year.

5438. (F.D.C. No. 40448. S. Nos. 56–193 M, 72–341 M, 72–781 M, 72–783 M, 72–794 M.)

INFORMATION FILED: 10–25–57, N. Dist. Ill., against **Del-Kar Drugs, Inc., Chicago, Ill., t/a Douglas Drugs, and Harry Simon (secretary-treasurer of the corporation) and Austin Jones (pharmacist).**

CHARGE: Between 2–21–57 and 4–8–57, *Metandren Linguets* were dispensed twice and *amphetamine sulfate tablets*, *Emmenatone capsules*, and *Dexedrine Sulfate capsules* were each dispensed once, without a prescription.

PLEA: Nolo contendere by corporation to all counts of information, by Austin Jones to dispensing *Metandren Linguets*, and by Harry Simon to dispensing the other drugs.

DISPOSITION: 11–7–57. Fine of $300, plus costs, against corporation, $225 against Simon, and $100 against Jones.

5439. (F.D.C. No. 40436. S. Nos. 48–481/4 M, 72–785/7 M.)

INFORMATION FILED: 9–27–57, N. Dist. Ill., against **Kaplan Drugs, Inc., Chicago, Ill., and George Ichiba (pharmacist) and Francis A. Nishimura (secretary of the corporation).**

CHARGE: Between 11–28–56 and 4–18–57, *Metandren Linguets*, *amphetamine sulfate tablets*, and *secobarbital sodium capsules* were each dispensed twice and *dextro-amphetamine sulfate capsules* were dispensed once, without a prescription.

PLEA: Nolo contendere by corporation to all counts of information, by Nishimura to counts 2 and 4 relating to dispensing of *Metandren Linguets* and *amphetamine sulfate tablets*, and by Ichiba to remaining counts of information.

DISPOSITION: 10–21–57. Corporation fined $300, plus costs, and each individual fined $200.

5440. (F.D.C. No. 39404. S. Nos. 52–202 M, 52–205 M, 52–223 M, 52–262 M, 52–270 M, 52–272 M, 52–322 M.)

INFORMATION FILED: 3–21–57, E. Dist. N.Y., against **Abraham Asch, t/a Klipp's Pharmacy, Garden City, N.Y., and Fred L. Chidester and Gustave Smith (pharmacists).**

CHARGE: Between 4–12–56 and 5–22–56, *AM Plus capsules* were dispensed twice and *Gantrisin tablets* were dispensed once without a prescription, and *Seconal Sodium capsules* and *Metandren Linguets* were each dispensed twice upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by Asch and Smith to one sale of *Seconal Sodium capsules*, *Gantrisin tablets*, *Metandren Linguets*, and *AM Plus capsules*, and by Chidester to one sale of *Seconal Sodium capsules*, *Metandren Linguets*, and *AM Plus capsules*.

DISPOSITION: 5–9–57. Asch fined $2,000; Chidester, $1,050; and Smith, $600.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 5421 TO 5440

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5429, 5435) Prosecution contested.
[2] (5428) Prosecution contested. Contains opinion of the court.

[1] (5429, 5435) Prosecution contested.

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D.D.N.J., F.D.C. 5441–5460 Issued May 1959

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5441–5460

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or trial; (2) a criminal proceeding terminated upon a plea of nolo contendere; and (3) an injunction proceeding terminated by consent to a permanent injunction decree. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *May 5, 1959.*

CONTENTS *

*For omission of, or unsatisfactory, ingredients statements, see Nos. 5443, 5448, 5450, 5460; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 5448, 5450, 5460; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 5448, 5450.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5441–5460

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use and (2) adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling; Section 502(l), the article was, or purported to be, or was represented as, a drug composed partly of penicillin, streptomycin, or a derivative thereof; and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507, and it was not exempt from such requirement by regulations promulgated under Section 507 (c) or (d).

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUG AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

5441. Laubach's No. 7 tablets. (F.D.C. No. 40553. S. No. 62–447 M.)

QUANTITY: 2 bulk drums containing a total of 52,100 tablets at Jersey City, N.J., in possession of Laubach Proprietary Medicines, Inc.

SHIPPED: 3–15–57, from Philadelphia, Pa., by Hance Bros. & White Co.

LABEL IN PART: (Drum) "Private Formula * * * P.F. 3687 * * * Laubach * * * Each Tablet Contains: Boric Acid 2 gr."

ACCOMPANYING LABELING: Placards headed "WHEN REST IS BROKEN" and "KEEP FIT."

RESULTS OF INVESTIGATION: The above-mentioned placards, which were on display in the dealer's store window, had been printed locally.

LIBELED: 8–12–57, Dist. N.J.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for all bladder and kidney irregularities; and 502(j)—when shipped and while held for sale, the article was dangerous to health

when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, (drum) "Dose: One or two tablets daily."

DISPOSITION: 9–18–57. Default—destruction.

5442. Form-Allure bust developers. (F.D.C. No. 40528. S. No. 74–321 M.)

QUANTITY: 9 devices at Portland, Oreg.

SHIPPED: 4–13–57 and 4–18–57, from Los Angeles, Calif., by Marbrook Co., Ltd.

LABEL IN PART: "The Marbrook Co. Ltd. form-allure of Hollywood."

ACCOMPANYING LABELING: Leaflets designated "Form-Allure" and printed sheets designated "Instructions and Suggestions."

RESULTS OF INVESTIGATION: The article consisted of two hemispherical plastic cups, approximately 4 inches in diameter at the open end, which were connected by means of rubber tubing to a treadle-operated vacuum pump. In use, the plastic cups were pressed against the chest wall so that each enclosed one of the breasts and the edge of the cup formed an airtight seal against the chest. Operation of the foot treadle caused a vacuum to be formed inside the plastic cups.

LIBELED: 8–28–57, Dist. Oreg.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the device was effective for developing the breasts, increasing the size of the breasts, and improving the appearance of the breasts; and 502(j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "One application daily should suffice but when convenient to do so, use twice daily—morning and evening. The time required for each user is determined by the length of time necessary to produce a flush over the area. When the breasts are pink—that is sufficient. In use, count ten to twenty strokes—remove cups (break vacuum) and wait for a few seconds—then repeat the operation. In the majority of cases three or four such applications is sufficient to produce the desired flush. Do not assume that if a short period is good, a longer period will be better. And, always control the length and number of strokes to your comfort. Regular, daily use for several months is suggested, then taper off and use only occasionally, as required."

DISPOSITION: 10–10–57. Default—delivered to the Food and Drug Administration.

DRUG FOR VETERINARY USE

5443. Hog fattener. (F.D.C. No. 40369. S. No. 227 M.)

QUANTITY: 76 75-lb. bags and 1 ton in bulk in Decatur, Nebr.

SHIPPED: 4–25–57, from Des Moines, Iowa, by Swift & Co.

LABEL IN PART: (Bag) "Swift's Hog Fattener."

RESULTS OF INVESTIGATION: Examination showed that the article was a pelleted medicated feed containing about 0.32 percent arsanilic acid.

LIBELED: 7–10–57, Dist. Nebr.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it was represented to possess, namely, .01 percent arsanilic acid; 502(e)(2)—the label of the article failed to bear the common or usual name

of each active ingredient since arsanilic acid was not declared; and 502(j)—the article was dangerous to health when used in the dosage and with the frequency or duration prescribed, recommended, or suggested in its labeling, namely, "It may be hand fed two or three times a day, or self fed by keeping it in a hopper at all times."

DISPOSITION: 8–12–57. Default—destruction.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

5444. Royal jelly capsules. (F.D.C. No. 40545. S. No. 74–956 M.)

QUANTITY: 51 boxes at San Marino, Calif., in possession of Eugene E. Thomas, t/a Ault Bee Farms.

SHIPPED: 7–9–57, from Weslaco, Tex., by Ault Bee Farms.

LABEL IN PART: "Royal Jelly 30 Capsules * * * Each capsule contains Net Weight: 25 Milligrams ____ Royal Jelly 60 Milligrams ____ Pure Honey 60 Milligrams ____ Organic Alfalfa 60 Mg. Organic Calcium & Phosphorous 60 Milligrams ____ Organic Wheat Germ This is a food, not a medicine. Ault Bee Farms, Box 1144, Pasadena, Calif."

ACCOMPANYING LABELING: Brochure entitled "Dr. Lisi prescribes Royal Jelly For His Holiness Pope Pius XII," a printed sheet headed "Ault Bee Farms * * * Dear Friend:" and a printed sheet headed "Ault Bee Farms * * * Here is an Excerpt From 'Here's Health' Magazine."

RESULTS OF INVESTIGATION: The brochure was received by the consignee from the Ault Bee Farms, Weslaco, Tex., and the printed sheets were printed locally for the consignee.

LIBELED: 8–6–57, S. Dist. Calif.

CHARGE: 502(a)—the designation "Royal Jelly" borne on the label of the article, when shipped, was misleading since the article contained 2 or more ingredients and was designated by the name of one but not all of such ingredients, even though the names of all such ingredients were stated elsewhere on the label; 502(a)—the labeling accompanying the article, when shipped and while held for sale, contained false and misleading representations that the article was capable of producing a state of well being and mental alertness; that the product contained all the vitamins and minerals needed by the body; and that it would prolong life, increase and sharpen appetite and sense of taste, lessen digestive difficulty, improve nervous balance, increase virility and sexual energy, increase ability to train and work harder, give one an increased feeling of youthfulness, prevent illness and debility, normalize the human mechanism, cure a wide variety of illnesses, reactivate body functions and check a tendency toward obesity, repair wastage, and rejuvenate body cells; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 8–27–57. Default—destruction.

5445. Royal jelly capsules. (F.D.C. Nos. 40345, 40346. S. No. 66–025 M.)

QUANTITY: 13 dozen 15-capsule bottles, 4 dozen 100-capsule bottles, and 4 additional 100-capsule bottles at San Francisco, Calif.

SHIPPED: Between 3–26–57 and 4–29–57, from New York, N.Y., by Tamara (a business organization).

LABEL IN PART: (Ctn.) "Royal Jelly * * * 50 mg. each * * * The Royal Jelly is guaranteed to be a natural product from the bee hive. This Royal Jelly from selected queen cells is not more than two days old after introducing the larvae, which gives the most active concentration."

ACCOMPANYING LABELING: Leaflets entitled "Theft From Queen Bee—Honey Jelly Keeps Child Ruler Young," reprints entitled "Reprints of Scientific New Reports on Royal Jelly," and books entitled "The Miracle of Royal Jelly."

LIBELED: 7–5–57, N. Dist. Calif.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective preventive and treatment for cancer, "what ails you," rejuvenation of the aged, keeping one young, adding years to one's life, healing ulcers, seborrhea, infectious hepatitis, stomatitis, eczema, acne, diabetes, and cirrhosis of the liver; that the article aids growth, fertility in women past the menopause, rejuvenation of sexual activity, stimulation of appetite, and elimination of nervous and vascular disorders; that the article would be effective for heart disease, liver ailments, hemorrhoids, increasing mental activity, pimples, blackheads, other skin blemishes, rejuvenating the tissues of the skin, and for other purposes.

505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 7–24–57. Default—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR VETERINARY USE

5446. Strep Pen spray (2 seizure actions). (F.D.C. Nos. 39696, 39697. S. Nos. 45–741/2 M.)

QUANTITY: 21 pints at Harmony, Md., and 57 pints at Laurel, Del.

SHIPPED: 7–5–56 and 9–10–56, from Vineland, N.J., by Eastern Laboratories, Inc.

LABEL IN PART: (Btl.) "Strep Pen Spray For Inhalation Therapy of Poultry * * * Contains 25 gm. Dihydrostreptomycin Base * * * and 5 million units of Penicillin G Potassium Contents—1 Pint * * * Manufactured for M & D Sales Co. Snow Hill, Md. [or "Twin Supply Service Co., Baltimore, Md."]."

RESULTS OF INVESTIGATION: Examination showed that the article had a potency of 2,000 units of penicillin G potassium per pint.

LIBELED: On or about 11–28–56, Dist. Md., and 11–21–56, Dist. Del.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; 502(a)—the label statement "Contains * * * 5 million units of Penicillin G Potassium [in] 1 Pint" was false and misleading; and 502(l)—the article was represented as a drug composed in part of penicillin and a streptomycin derivative; it was not from a batch with respect to which a certificate had been issued pursuant to law; and it was not exempt from such requirement.

DISPOSITION: 1–28–57 and 1–30–57. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

5447. Elip tablets. (F.D.C. No. 34887. S. Nos. 37-389/90 L.)

QUANTITY: 39 bags, 1,200 tablets each, at Baldwin, N.Y., in possession of Baldwin Laboratories, and 94 12-tablet vials at Baldwin, N.Y., in possession of Elip Distributing Co.

SHIPPED: 6-6-52, from East Newark, N.J.

LABEL IN PART: (Bag) "Elip Tablet"; (vial) "Elip Tablets * * * Active Ingredients: Potassium Bitartrate, Sulfur, Rhubarb."

ACCOMPANYING LABELING: Window sign bearing the words "Elip For Piles" and counter display placards bearing the words "An Internal Preparation For The Relief of Piles."

RESULTS OF INVESTIGATION: The tablets in the bags represented the remainder of a bulk shipment which had been made to Baldwin Laboratories at Baldwin, N.Y., from East Newark, N.J.; and the tablets in the vials represented a portion of such bulk shipment which had been sold by Baldwin Laboratories to Elip Distributing Co. and repackaged into vials by that company.

The above-described window sign was on display in the window of Baldwin Laboratories, and the counter display placard was used by the Elip Distributing Co. in preparing the vials of tablets for sale. The vials were attached to the placards in units of six.

LIBELED: 3-20-53, E. Dist. N.Y.; amended libel 1-10-55.

CHARGE: 502(a)—while held for sale, the labeling of the article in the bags and vials contained false and misleading representations that the article was an adequate and effective treatment for piles and the discomfort and itching of rectal irritation caused by piles; and 502(f)(2)—the labeling of the article failed to bear a warning against its use for bleeding piles.

DISPOSITION: The Elip Distributing Co. and Ira Lichtenstein, t/a Baldwin Laboratories, claimants, filed an answer to the original libel, denying that the article was misbranded as alleged. Interrogatories were served by the Government upon the claimants on 10-20-53; and the claimants, without answering the interrogatories, made a motion for summary judgment. The matter was argued before the court on 1-13-54, and on 2-11-54 the court handed down the following decision in denial of the motion:

BYERS, *District Judge:* "This is a claimant's motion in a condemnation proceeding under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301, et seq.) for summary judgment.

"The basis of the motion is a holding by the U.S. Post Office Department that the subject matter of the libel was not falsely and fraudulently labeled.

"Fraud is not alleged in the libel, nor was such an allegation requisite under the law. *U.S.* v. *5 cases, etc.*, 156 Fed (2) 493 Cf. *U.S.* v. *Dotterweich*, 320 U.S. 277.

"It is clear that such a departmental holding is not res judicata.

"Motion denied. Settle order."

Following the decision, the claimants filed answers to the interrogatories. The amended libel was filed, to which the claimants filed an answer, denying that the article was misbranded; they again advanced the defense of res judicata based upon the prior Post Office proceedings. The Government moved to strike the allegations in the answer relating to the res judicata defense; and on 9-6-55, the court granted the Government's motion to strike.

The case came on for trial before the court without a jury on 12–18–56; and at the conclusion of the trial, the case was taken under advisement by the court. On 4–5–57, the court handed down the following opinion (150 F. Supp. 648):

BRUCHHAUSEN, *District Judge:* "The libelant instituted this action to condemn a quantity of drugs and advertising material, upon the ground that the drugs were misbranded or mislabelled, in violation of the Pure Food and Drug Act.

" 'The purpose of the law is to protect the public, the vast multitude which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze. It was enacted to make self-medication safer and more effective, and to require that drugs moving in interstate commerce be properly labeled so that their use as prescribed may not be dangerous to the health of the user.' *United States* v. *62 Packages, etc.*, 48 F. Supp. 878, 887, affirmed 142 F. 2d 107, certiorari denied 323 U.S. 731.

"The term 'labeling' applies to the matter printed or written upon the article itself, and upon the containers or wrappers accompanying it (21 U.S.C. 321(m)). A drug is deemed misbranded 'if its labeling is false or misleading in any particular' also if the labeling fails to include adequate warnings as to its use (21 U.S.C. 352(a)(f)).

"It is not disputed that the claimant Ira Lichtenstein, doing business as Baldwin Laboratories, conceived the formula for the drugs or tablets in question; that the formula consisted of a mixture of flowers of sulphur, rhubarb root and cream of tartar; that the said claimant engaged Jabert Pharmacal Company, Inc. to manufacture the tablets, and that the said claimant contracted with the claimant Elip Distributing Corporation to market them, including packaging and advertising.

"The contention is that in the process of marketing the tablets, the claimants deceived the public in asserting that the tablets would relieve the ailment, known as 'Piles.'

"It is interesting to note that the manufacturer made no such assertion. Its label on the gross shipment to the distributors made no mention of such ailment but designated the tablets as 'laxatives.' The distributors did not use that label but prepared a different label, inserted it in each package or vial of 12 tablets, reading, in part:

> Elip Tablets—A palliative treatment for discomfort and itching of rectal irritation caused by piles.

"The counter display cards contained the statement:

> An internal preparation for the relief of piles. Price 62. Elip Reg. U.S. Pat. Off.

"A neon sign in the window of Baldwin Laboratories read: 'Elip for Piles.'

"During the trial, the claimants stipulated that the labeling should contain a warning against using the tablets for bleeding piles.

" 'Elip,' the designation used by the claimants in promoting the product is 'pile' spelled backwards.

"The three medical experts produced by the Government, expert proctologists, testified that Elip tablets are laxatives and not particularly mild and that the only complete cure for piles is surgery.

"The claimant Lichtenstein, a pharmacist, admitted that surgery was the only known complete cure for piles, but denied that Elip was held out as a cure. He said that he conceived the tablet as a mild laxative softening the digested matter passing over the pile area, and containing an astringent for washing the affected area.

"Either he or his medical witness also asserted the qualities of the tablets were such that the laxative did not operate until it reached the large intestine, thus guaranteeing a complete movement and that there were certain germ killing qualities in the drug.

"Apparently no certain medication has been discovered to date which will cure piles nor are the specific causes known. They are known as hemorrhoids in medical terminology, and consist of swollen veins in the lower end of the large intestine, or anus, brought on by such causes as constipation, infection, overstraining, heredity, childbirth, tension, worry and diet.

"If they protrude, they are known as external as distinguished from internal hemorrhoids, and when dilated they are very painful. Very often they bleed. Temporary relief comes with the lessening of congestion. Sometimes, as with common colds, piles cure themselves.

"A controlled experiment was conducted at Bellevue Hospital by Dr. Max P. Cowett, a distinguished proctologist. He testified that twenty-eight patients, interspersed between hospital and clinic patients were treated with Elip tablets for a period of almost four months. An additional twenty were given placebos in the form of milk sugar tablets. The results were uncomplimentary to Elip. Several of those using the tablets grew worse, or complained of abdominal cramps, with increased bowel movements, and tenesmus, or bowel frustration. The experiment with some patients had to be discontinued. Several required either surgery or sclerosing. None of the patients on either the Elip or the placebo benefited during the treatment.

"Various newspaper and periodical advertisements were submitted in evidence as proof of the intent of the labels, although not as evidence of the labeling itself. Such evidence is competent. *Colgrove* v. *United States*, 9 Cir., 176 F. 2d 614, certiorari denied 338 U.S. 911; *Research Laboratories* v. *United States*, 167 F. 2d 410, certiorari denied 335 U.S. 843; *United States* v. *Vitamin Industries, Inc.*, D.C. Nebr., 130 F. Supp. 755.

"In newspaper advertising and throwaways, the claimant made claims for the tablets such as: 'Piles checked in 72 hours with tablets * * * in 72 hours the bleeding stopped * * * Elip brings sure relief from pile misery * * * the only internal pile remedy.'

"It is plain that the claimants entered into a campaign of 'bait advertising.' A product, manufactured as a laxative, without any changes by the promoters, is held out to the unsuspecting public as a remedy for another condition, piles. The recklessness of the claimants and their utter disregard of those whom they catered to is evidenced by their admission that the tablets could not aid anyone afflicted with bleeding piles. That the element of large profit was not absent from this enterprise is inferable. The tablets cost the claimants about one-tenth of a cent each and were sold by the claimants at $2 per package of 12 tablets. It is fairly apparent that if the claimants had informed the purchasers that the product was nothing more than a laxative, they would have been obliged to compete with the large number of producers of that article and would not have interested the pile sufferers.

"A decree is directed for the relief demanded in the libel."

In accordance with the above opinion, judgment of condemnation was entered on 6–10–57, and the product was ordered destroyed.

5448. **Multizyme.** (F.D.C. No. 40552. S. No. 74–325 M.)

QUANTITY: 777 unlabeled 8-oz. btls. and 1,596 unlabeled 4-oz. btls. at Seattle, Wash., in possession of Enzymes Products Co., Inc.

SHIPPED: 2–8–57 and 2–13–57, from Anaheim, Calif., by Ward Erickson.

ACCOMPANYING LABELING: Loose labels designated as "Multizyme Formula W.E. 8 ["or 4"] fl. ozs.," leaflets designated as "The Revolutionary New Multizyme * * * Put your Health in Balance," and order cards designated as "Multizyme * * * Special Trial Offer."

RESULTS OF INVESTIGATION: The accompanying labeling of the article was printed locally for the consignee.

LIBELED: 8–12–57, W. Dist. Washington; amended libel 8–14–57.

CHARGE: 502(a)—the name "Multizyme," by which the drug was designated while held for sale, was misleading since it suggested the presence of multiple enzymes in the article as the valuable factor needed in a food supplement for human nutrition, whereas such was not the fact; and, in addition, the leaflets and order cards accompanying the article, while held for sale, contained false and misleading representations that the article would keep the bloodlines of the body clean and so protect one from high blood pressure, and that it would correct the suffering caused by the lack of balance of forces within the body cells; 502(b) (1) and (2)—when shipped, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502(e) (2)—when shipped, the article failed to bear a label containing the common or usual name of each active ingredient contained therein; and 502(f) (1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: 12–23–57. Consent—claimed by Lee V. Schneider, Seattle, Wash., and relabeled.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5449. Posterior pituitary injection. (F.D.C. No. 40200. S. No. 54–805 M.)

QUANTITY: 99 1-cc. vials at Lynwood, Wash.

SHIPPED: 3–19–57, from Philadelphia, Pa., by Lustgarten Laboratories, Inc.

LABEL IN PART: "1 cc Amp. Pituitary Extract 10 U. S. P. Units (Obstetrical) * * * Control No. 020477 * * * Vitamix Corporation Philadelphia, Pa."

RESULTS OF INVESTIGATION: Analysis showed that the potency of the article was less than 0.062 U. S. P. posterior pituitary units per cubic centimeter.

LIBELED: 5–16–57, W. Dist. Wash.

CHARGE: 501(b)—the strength of the article, when shipped, differed from the standard for "Posterior Pituitary Injection" set forth in the United States Pharmacopeia; and 502(a)—the label statement "1 cc Amp. Pituitary Extract 10 U. S. P. Units" was false and misleading as applied to a product, the potency of which is less than 10 U. S. P. posterior pituitary units per cubic centimeter.

DISPOSITION: 7–23–57. Default—destruction.

5450. Progesterone-estrogen. (F.D.C. No. 40367. S. No. 65–086 M.)

QUANTITY: 31 vials in a carton at Columbus, Ohio.

SHIPPED: 4–12–57, from Sarasota, Fla., by Stillco Laboratories.

LABEL IN PART: (Ctn.) "Stillco Laboratories * * * Sarasota, Florida, 35 x 10 cc — Control #956 — Progesterone-Estrogen In Sesame Oil — Intramuscular — Per CC Progesterone USP 25 MGM — Estrogens (95–98% Estrone) 25,000 I. U."

RESULTS OF INVESTIGATION: Analysis showed that the article was an oil solution containing 21.6 percent of the declared amount of estrogens.

LIBELED: 7–2–57, S. Dist. Ohio.

*See also Nos. 5443, 5446.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 25,000 I. U. estrogens per cubic centimeter; 502(a)—the carton label statement "Per CC * * * Estrogens * * * 25,000 I. U." was false and misleading as applied to the article, which contained 21.6 percent of the declared amount of estrogens; 502(b)(1)—the label of the article failed to bear the name and place of business of the manufacturer, packer, or distributor; 502(b)(2)—the label of the article failed to bear an accurate statement of the quantity of contents; and 502(e)(2)—the label of the article failed to bear the common or usual name of each ingredient.

DISPOSITION: 8–9–57. Default—destruction.

5451. Pyrilamine maleate Prolongsules. (F.D.C. No. 40358. S. No. 41–858 M.)

QUANTITY: 1 drum containing 24,935 capsules, and 238 12-capsule vials at Buffalo, N.Y.

SHIPPED: 3–30–56, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Drum) "Pyrilamine Maleate Prolongsules * * * Delayed Action, Time Disintegrating Capsules * * * Released Gradually * * * Over A Period of Approximately 8 Hours * * * Each Prolongsule Contains: Pyrilamine Maleate 75 Mgm."

RESULTS OF INVESTIGATION: Analysis showed that the capsules of the article did not allow gradual release of pyrilamine maleate over a period of approximately 8 hours, but, instead, the pyrilamine maleate was released in a much shorter time. Examination showed that the capsules in vials had been repacked from the bulk drum.

LIBELED: 6–27–57, W. Dist. N. Y.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it was represented to possess since the active ingredient was not gradually released over an 8-hour period, but was, instead, released in a much shorter time; and 502(a)—the statements in the label which represented and suggested that the active ingredient was gradually released over an 8-hour period were false and misleading.

DISPOSITION: 8–15–57. Default—destruction.

5452. Bennett Arben capsules. (F.D.C. No. 40199. S. Nos. 74–867/70 M.)

QUANTITY: 24,000 capsules of *Formula No. 2*, 23,000 capsules of *Formula No. 6A*, 24,000 capsules of *Formula No. 8A*, and 17,000 capsules of *Formula No. 12A* at Santa Monica, Calif. The capsules were packed in bulk drums.

SHIPPED: On an unknown date, from Miami Beach, Fla., by Arthur Bennett Pharmaceuticals.

LABEL IN PART: "Bennett Arben Capsules Formula No. 2 * * * Amphetamine Sulfate 1.2 mgm. * * * Lot No. 2016," "Bennett Arben Capsules Formula No. 6A * * * Amphetamine Sulfate 1.8 mgm. * * * Lot. No. 3010," "Bennett Arben Capsules Formula No. 8A * * * Amphetamine Sulfate 2.5 mgm. * * * Lot No. 3008," and "Bennett Arben Capsules Formula No. 12A * * * Amphetamine Sulfate 5 mgm. * * * Lot No. 3014."

RESULTS OF INVESTIGATION: Examination showed that the capsules contained the following amounts of amphetamine sulfate per capsule: *Formula No. 2*—2.3 mgs., *Formula No. 6A*—3.3 mgs., *Formula No. 8A*—4.9 mgs., and *Formula No. 12A*—9.8 mgs.

LIBELED: 5–16–57, S. Dist. Calif.

CHARGE: 501(c)—the strength of the capsules, when shipped, differed from that which they purported and were represented to possess.

DISPOSITION: 7–2–57. Default—destruction.

5453. Hemoton Forte. (F.D.C. No. 40284. S. No. 81–743 M.)

QUANTITY: 75 10-cc. vials at Metairie, La.

SHIPPED: 12–18–56, from Decatur, Ill.

LIBELED: 6–17–57, E. Dist. La.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it was represented to possess, namely, 60 micrograms of cyanocobalamin per cubic centimeter; and 502(a)—the label statement "Each cc contains Vitamin B–12—(From Liver Injection) Equivalent To: Cyanocobalamin 10 mcgm—and Cyanocobalamin (added) 50 mcgm" was false and misleading as applied to an article which had a potency of less than 40 micrograms of cyanocobalamin per cubic centimeter.

DISPOSITION: 8–15–57. Default—destruction.

5454. Prophylactics. (F.D.C. No. 40361. S. No. 72–915 M.)

QUANTITY: 720 2-unit pkgs. at Evanston, Wyo.

SHIPPED: 6–18–57, from Brooklyn, N.Y., by J. Schoenbach.

LABEL IN PART: "Royal Knight Prophylactics."

RESULTS OF INVESTIGATION: Examination showed that 5.9 percent of the article was defective in that it contained holes.

LIBELED: 7–2–57, Dist. Wyo.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported to possess; and 502(a)—the label statement "Prophylactics" was false and misleading as applied to an article that contained holes.

DISPOSITION: 8–22–57. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

5455. Homeopathic drugs. (Inj. No. 298.)

COMPLAINT FOR INJUNCTION FILED: 3–27–56, E. Dist. Wis., against Louis Pauly, Milwaukee, Wis.

NATURE OF BUSINESS: The complaint alleged that the defendant was engaged in selling and distributing various *homeopathic drugs* in the form of tablets of various strengths and designated by name as follows: Calcium Fluoride (Calcarea Fluorica), Calcium Phosphate (Calcarea Phosphorica), Calcium Sulfate (Calcarea Sulphurica), Iron Phosphate (Ferrum Phosphate), Sodium Chloride (Natrum Muriaticum), Potassium Chloride (Kali Muriaticum), Sodium Sulfate (Natrum Sulphuricum), Silica (Silicea or Quartz), Potassium Phosphate (Kali Phosphate), Potassium Sulfate (Kali Sulphuricum), Magnesium Phosphate (Magnesium Phosphoricum), and Sodium Phosphate (Natrum Phosphoricum).

It was alleged that while these drugs were held for sale by the defendant, after shipment in interstate commerce, the defendant caused the drugs to be accompanied by the following pieces of labeling: Blotters entitled "Professional Comments on the Bio-Chemic System of Medicine" and "My Proposed Cover

*See also Nos. 5441, 5442, 5444–5451, 5453, 5454.

Page for Letter No. 16 November, 1950"; booklets entitled "My Open Letter No. 12," "Supplement Letter No. 13 November, 1949," "Supplement Letter No. 19 April, 1952," "Supplement Letter No. 6 June, 1945," "What the Forgotten 12 Tissue Remedies * * * Can Heal in The Human Body," "Supplement Letter No. 15 November, 1949," "Letter No. 22 January, 1954," "My Booklet Letter No. 24 April, 1955," and "My Booklet Letter No. 25 * * * The Biochemic System of Medicine November, 1955"; and leaflets entitled "Letter No. 13 September, 1948," "Excerpts From My Coming Letter No. 14 for 1949," "I am Calling This Sheet My #17 Letter July, 1951," "Letter No. 18," "Louis Pauly," "January, 1954 Supplement Letter No. 21A," "Mr. Roy C. Frank * * * January, 1953," "Supplement Letter No. 20 January, 1953," "Supplement Letter No. 21 * * * July, 1953," and "Letter No. 7 March, 1946."

CHARGE: The complaint charged that the defendant was violating the Act by his acts of causing the above-mentioned labeling to accompany the above-named drugs, in that such acts were done while the drugs were held for sale after shipment in interstate commerce and resulted in the drugs being misbranded as follows: 502(a)—the accompanying labeling of the drugs contained false and misleading representations that the drugs were adequate and effective treatments for the following diseases, symptoms, and conditions: tuberculosis, dermatitis, bronchitis, infantile paralysis (polio), fungus infections, chronic diseases, itching, eczema, prostatic hypertrophy, skin rashes, sores, all skin diseases, pyorrhea, arthritis, Hodgkin's disease, piles, boils, asthma, constipation, headaches, epilepsy, earache, tumors, pneumonia, abscess of the rectum, coughs, colds, psoriasis, acne, anemia, bed wetting, carbuncles, dyspepsia, impetigo, nervousness, fever, insomnia, neuritis, paralysis, prostate trouble, sinus diseases, stys on the eyes, fistula, high and low blood pressure, menopausal symptoms, leg cramps, lymphoblastoma, cancer, leukemia, Buerger's disease, colitis, nervous and mental breakdown, gallbladder trouble, glandular affections, female tumors, sciatica, diabetes, rheumatism, jungle rot, tonsillitis, appendicitis, breast cancer, shingles, multiple sclerosis, warts, ulcers, Bright's disease, heart trouble, gallstones, hay fever, other allergic diseases, muscular dystrophy, virus infections, mumps, and stomach ulcers.

The complaint alleged also that if the defendant was forced by an injunction to refrain from using the above-mentioned accompanying labeling on the drugs distributed by him, the defendant would not discontinue such distribution but would, unless enjoined, continue to distribute the drugs, while held for sale after shipment in interstate commerce, without labeling stating the conditions and purposes for which the drugs were intended; and that, in such case, the drugs would be misbranded under 502(f)(1), in that their labelings would fail to bear adequate directions for use because of the omission from such labeling of statements of the conditions and purposes for which the drugs were intended.

The complaint alleged also that the defendant was well aware that his activities were violative of the Act; that 3 seizures of *homeopathic drugs* in his possession had been made since 1952; that a Notice of Hearing had been issued to him in 1955, charging that his drugs were misbranded; and that he had been warned of the requirements of the Act at 6 different establishment inspections.

DISPOSITION: On 4–9–56, upon the failure of the defendant to appear, a preliminary injunction was entered pending the final determination of the action. On 5–31–57, the defendant having consented, the court entered a decree of permanent injunction enjoining the defendant from doing any of the following acts with respect to the above-named drugs or any other drugs of similar composition while such drugs are being held for sale after shipment in interstate commerce:

(a) causing such drugs to be accompanied by the above-mentioned labeling;
(b) causing such drugs to bear labels or be accompanied by labeling containing the representations described above and any other false and misleading representations; and
(c) causing the omission from the labeling of such drugs of statements of the purposes and conditions for which the drugs are intended.

5456. Homeopathic drugs. (F.D.C. No. 38435. S. No. 5–333 M.)

QUANTITY: The following amounts of *homeopathic drugs* at Milwaukee, Wis., in possession of Louis Pauly: 2 1-lb. cartons of Homoeopathic Trituration of 2 X Calcarea Fluorica; 6 2-oz. btls. and 4 1-lb. btls. of E & K Homoeopathic Tablet Triturate Calcarea Fluorica (Calcium Fluoride) 6 X; 20 2-oz. btls. and 6 1-lb. btls. of E & K Homoeopathic Tablet Triturate Calcarea Fluorica (Calcium Fluoride) 12 X; 1 1-oz. btl., 5 2-oz. btls., 1 4-oz. btl., and 3 1-lb. btls. of E & K Homoeopathic Tablet Triturate Calcarea Phosphorica (Calcium Phosphate) 6 X; 1 1-lb. carton of E & K Homoeopathic Tablet Triturate Calcarea Sulphurica (Calcium Sulfate) 3 X; 11 2-oz. btls. and 9 1-lb. btls. of E & K Homoeopathic Tablet Triturate Calcarea Sulphurica (Calcium Sulfate) 6 X; 4 1-lb. cartons and 1 5-lb. carton of Homoeopathic Trituration of 2 X Ferrum Phosphate; 1-lb. carton of Homoeopathic Trituration of 6 X Ferrum Phosphate; 17 2-oz. btls. and 15 1-lb. btls. of E & K Homoeopathic Tablet Triturate Ferrum Phosphate 6 X; 12 2-oz. btls. and 6 1-lb. btls. of E & K Homoeopathic Tablet Triturate Ferrum Phosphoricum (Iron Phosphate) (or Ferrum Phosphate) 12 X; 12 2-oz. btls. and 16 1-lb. btls. of E & K Homoeopathic Tablet Triturate Kali Muriaticum (Potassium Chloride) 6 X; 9 2-oz. btls. and 11 1-lb. btls. of E & K Homoeopathic Tablet Triturate Kali Phosphoricum (Potassium Phosphate) 3 X; 8 2-oz. btls. and 9 1-lb. btls. of E & K Homoeopathic Tablet Triturate Kali Sulphuricum (Potassium Sulfate) 6 X; 12 2-oz. btls. and 4 1-lb. btls. of E & K Homoeopathic Tablet Triturate Magnesium Phosphoricum (Magnesium Phosphate) 3 X; 15 1-lb. btls. of E & K Homoeopathic Tablet Triturate Natrum Muriaticum (Sodium Chloride) 3 X; 8 2-oz. btls. and 8 1-lb. btls. of E & K Homoeopathic Tablet Triturate Natrum Phosphoricum (Sodium Phosphate) 6 X; 1 1-lb. carton of E & K Homoeopathic Tablet Triturate Natrum Sulphuricum (Sodium Sulfate) 1 Gr. 3 X; 8 2-oz. btls. and 3 1-lb. btls. of E & K Homoeopathic Tablet Triturate Natrum Sulphuricum (Sodium Sulfate) 6 X; 6 1-lb. btls. of E & K Homoeopathic Tablet Triturate Silicea (Silica) 3 X; 17 2-oz. btls. and 5 1-lb. btls. of E & K Homoeopathic Tablet Triturate Silicea (Silica) 6 X; 8 2-oz. btls. and 5 1-lb. btls. of E & K Homoeopathic Tablet Triturate Silicea (Silica) 12 X; 7 4-oz. btls. of E & K Compound Tablets Homoeopathic Cal. Fl. 6 X, Fer. Phos. 6 X, Kali Mur. 6 X, Kali Phos. 3X, Magnesium Phos. 3X; 4 2-oz. btls. of E & K Compound Tablets Homoeopathic Calcarea Fluor. 6 X, Ferrum Phos. 6 X, Kali Muriate 6 X, Silicea 6 X; 7 2-oz. btls. and 3 1-lb. btls. of E & K

Tablet Triturates Homoeopathic Calc. Fl. 12 X, Ferr. Phos. 12 X, Silicea 12 X; 8 2-oz. btls. and 10 1-lb. btls. of E & K Compound Tablets Homoeopathic Calcium Phosphate 6 X 1 parts, Calcium Fluoride 6 X 1 parts, Calcium Sulfate 6 X 1 parts, Ferrum Phosphate 6 X 3 parts, Magnesium Phosphate 3 X 3 parts, Silicea 6 X 1 parts, Kali Muriate 6 X 1 parts, Kali Phosphate 3 X 3 parts, Kali Sulfate 6 X 1 parts, Natrum Muriate 6 X 1 parts, Natrum Phosphate 6 X 1 parts, Natrum Sulfate 6 X 1 parts; 7 1-lb. btls. of Homoeopathic Trituration of Ferr. Phos. 6 X 3 parts, Kali Mur. 6 X 1 part, Kali Sulf. 6 X 1 part, Natr. Mur. 6 X 3 parts; 35 2-oz. btls. and 5 1-lb. btls. of E & K Homoeopathic Compound Tablets Ferr. Phos. 6 X 2 parts, Nat. Mur. 6 X 2 parts, Kali Sulf. 6 X 1 part; 2 1-oz. btls., 24 2-oz. btls., and 8 1-lb. btls. of E & K Compound Tablets Homoeopathic (or Tablet Triturate Homoeopathic) Ferrum Phos. 6 X, Kali Phos. 3 X, Magnesium Phos. 3 X; 3 2-oz. btls. and 15 1-lb. btls. of E & K Compound Tablets Homoeopathic Ferrum Phos. 6 X 3 parts, Kali Phos. 3 X 3 Parts, Magnesium Phos. 3 X 3 Parts, Kali Muriate 6 X 1 Part; 1 2-oz. btl. and 11 1-lb. btls. of E & K Compound Tablets Homoeopathic Kali Phos. 3 X, Magnesium Phos. 3 X, Silicea 6 X; 19 2-oz. btls. and 1 1-lb. btl. of E & K Compound Tablets Homoeopathic Natr. Mur. 3 X, Natr. Phos. 3 X, Natr. Sulf. 3 X, Silicea 60% 6 X, and Fluor. 40% 6 X; 2 1-lb. btls. of E & K Compound Tablets Homoeopathic 1 gr. Natrum Phos. 6 X, Natrum Sul. 6 X, Calc. Fluor. 6 X, Kali Mur. 6 X, Ferrum Phos. 6 X; 7 1-lb. btls. of E & K Compound Tablets Homoeopathic Nat. Phos. 6 X, Nat. Sulf. 3 X, Cal. Fl. 3 X, Kali Mur. 3 X, Fer. Phos. 6 X, Kali Sulf. 6 X, Silicea 6 X Colored Red; 3 1-lb. btls. of E & K Tablet Triturates Homoeopathic Silicea 6 X. . . . 60 per cent, Cal. Fluor. 6 X. . . . 40 per cent; and 14 2-oz. btls. of E & K Tablet Triturates Homoeopathic Silicea 6 X 2 parts, Fer. Phos. 6 X 3 parts, Kali Sulf. 6 X 1 part Colored Green.

SHIPPED: Between 8–31–54 and 8–9–55, from Chicago, Ill.

ACCOMPANYING LABELING: Booklets entitled "Supplement Letter No. 6 June 1945," "Supplement Letter No. 19 April 1952," "Letter No. 22 January 1954," and "My Booklet Letter No. 24 April 1955"; leaflets entitled "Letter No. 13," "Excerpts From My Coming Letter No. 14 for 1949," "Supplement Letter No. 20 January 1953," and "January 1954 Supplement Letter No. 21A"; mimeographed 3-sheet letters entitled "Letter No. 7 March 1946"; leaflet form letter dated January 1953; and blotters headed "Professional Comments On The Bio-Chemic System Of Medicine."

RESULTS OF INVESTIGATION: The above-mentioned accompanying labeling was printed in the Milwaukee area for Louis Pauly.

LIBELED: 9–15–55, E. Dist. Wis.

CHARGE: 502(a)—the accompanying labeling of the articles, while held for sale, contained false and misleading representations that the articles constituted adequate and effective treatments for tuberculosis, dermatitis, bronchitis, infantile paralysis (polio), fungus infections, chronic diseases, itching, eczema, prostatic hypertrophy, skin rashes, sores, all skin diseases, pyorrhea, arthritis, Hodgkin's disease, piles, boils, asthma, constipation, headaches, epilepsy, earache, tumors, pneumonia, abcess of the rectum, coughs, colds, psoriasis, acne, anemia, bed wetting, carbuncles, dyspepsia, impetigo, nervousness, fever, insomnia, neuritis, paralysis, prostate trouble, sinus diseases, stys on the eyes, fistula, high and low blood pressure, menopausal symptoms, leg cramps, lymphoblastoma, cancer, leukemia, Buerger's disease, colitis, nervous and mental breakdown, gallbladder trouble, glandular affections, female tumors,

sciatica, diabetes, rheumatism, jungle rot, tonsillitis, appendicitis, breast cancer, shingles, multiple sclerosis, warts, ulcers, Bright's disease, heart trouble, gallstones, hay fever, other allergic diseases, muscular dystrophy, virus infections, mumps, and stomach ulcers.

DISPOSITION: 11–13–56. Default—destruction.

5457. Multivitamin tablets. (F.D.C. No. 40314. S. No. 57–204 M.)

QUANTITY: 1 carton containing 88 20-tablet btls. at Atlanta, Ga., in possession of R. A. McLain & Associates.

SHIPPED: 2–8–57, from Chicago, Ill.

ACCOMPANYING LABELING: Leaflets entitled "Pega Palo * * * Please excuse this form letter" and a number of loose labels reading, in part, "$20.00 Pega Palo 20 Capettes For The 'Healthy' Feeling Pega Palo Atlanta 8, Ga. * * * A combination of fat and water soluble vitamins with essential minerals and lipotropic factors. Each capsule contains: Vitamin A * * * 25,000 USP Units Vitamin D * * * 5,000 USP Units Vitamin C * * * 150 mg. Vitamin B_1 * * * 10 mg. Vitamin B_2 * * * 5 mg. Vitamin B_6 * * * 1 mg. Calcium Pantothenate 10 mg."

RESULTS OF INVESTIGATION: The loose labels were printed locally for the consignee, which intended to affix the labels to the bottles containing the tablets.

LIBELED: On or about 6–17–57, N. Dist. Ga.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article contained Pega Palo (*Rhynchosia pyramidalis*) and that the formula for Pega Palo was registered and on file with the United States Food and Drug Administration.

DISPOSITION: 7–18–57. Default—destruction.

5458. Rondeau's Medicine. (F.D.C. No. 40201. S. No. 50–178 M.)

QUANTITY: 10 btls. at North Franklin, Conn.

SHIPPED: 10–5–56, from Au Sable Forks, N.Y., by an unkown shipper.

LABEL IN PART: (Btl.) "Rondeau's Medicine Contains Herbs and Vitamins A and D Vitamin A: 180 International Units per Millilitre Vitamin D: 17.5 International Units Per Millilitre * * * Directions: One tablespoon full before each meal and before retiring, in a little water if desired. Children from seven to fifteen years: one teaspoon full four times a day. Children under seven years: five drops three times a day * * *. Manufactured by Antibitol Company Limited, 4211 St. Catherine St. West, Westmount, Montreal 6, Que."

ACCOMPANYING LABELING: Leaflets entitled "Dear Doctor Rondeau," "Prenez Le Remede Rondeau," and "Worried about Your Health?"

LIBELED: 5–15–57, Dist. Conn.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was effective in the treatment of affections of the respiratory tract; colds, eczema, skin conditions, impure blood, and weak muscles; impaired functioning of the gallbladder, kidneys, lungs, and liver; and varicose veins, skin ulcers, carbuncles, boils, infection, psoriasis, asthma, and arthritis.

DISPOSITION: 8–8–57. Default—destruction.

5459. Wildunger herb tea. (F.D.C. No. 40302. S. No. 60–274 M.)

QUANTITY: 2 100-lb. drums at Detroit, Mich., in possession of Alfred A. Hofmann, t/a Botanical Mail-Order House.

SHIPPED: 2–25–57, from New York, N.Y.

LABEL IN PART: (4-oz. size container) "Wildunger Brand Herb Tea Contains: Bean Shells, Corn Silk, Birch Leaves, Cranberry Leaves, Shave Grass, Peppermint Leaves, Buchu Leaves, Licorice Root, Anise Seed * * * This well blended formula was originated in Bad Wildungen (Germany), one of the world's most famous spas * * * Prepared for and Distributed by Botanical Products, Detroit 19, Michigan U.S.A."

ACCOMPANYING LABELING: Leaflets entitled "Are You Dieting? Are You On A Salt-Fat-Starch or Sugar Restricted Diet?" "Note: Wildunger Brand Herb Tea contains 75% of the herbs mentioned in this reprint * * *," "General Dietetic Rules by Dr. Marc Royal Counselor and County Physician at Bad Wildungen, Germany * * *," "and "Wildunger Brand Herb Tea * * * It's Here At Last!"

RESULTS OF INVESTIGATION: The article in the drums was to be repacked by the consignee into containers holding 4 ozs. and labeled as described above. The accompanying labeling referred to above was used by the consignee in direct mail advertising to customers and prospective customers or was enclosed in packages mailed to customers.

LIBELED: 6–4–57, E. Dist. Mich.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was effective in the treatment of diabetes, diseases of the urinary organs, and for improving the health.

DISPOSITION: 7–29–57. Default—destruction.

5460. Dried herbs. (F.D.C. No. 39188. S. Nos. 78–147 L, 86–525/7 L, 88–082 L.)

INFORMATION FILED: 5–10–56, E. Dist. Mich., against Wyatt E. Brown, t/a, W. E. B. Chemical & Products Co., Detroit, Mich.

SHIPPED: Between 6–1–54 and 8–11–54, from Michigan to Minnesota, Ohio, and West Virginia.

LABEL IN PART: (Bag) "For Sugar Diabetes Vinca Major Urtica Dioica Directions Place one teaspoonful in a cup. Pour boiling water over. Let stand 12 hours minutes. Strain and drink one cupful morning and night," "For Asthma * * * Symplocarpus Foetidus Eriodictyon Californicum Viburnum Apulus Directions Place one teaspoonful in a cup. Pour boiling water over. Let stand 12 hours minutes. Strain and drink one cupful morning and night," "X–Special Blood Tonic Podophyllum Peltatum And Other Herbs * * * Dose: 1 Teaspoonful Morning and Night," "Special Nerve Tonic * * * Valeriana Officinalis, Scutellaria Lateriflora, Indian Sage, Lobelia Inflata, Mentha Piperita, Cypripedium, Pubescens, Serpentaria Aristolopia, Humulus, Lupulus, Kolanut, Lousewort, Nipta, Cataria Dose: 1 Teaspoonful Morning and Night," or "Prostate Gland Plantago Majoo Dose: 1 Teaspoonful Morning and Night."

CHARGE: 502(a)—the labeling of the articles, when shipped, contained false and misleading representations and suggestions that the articles would be adequate and effective in the treatment of diabetes, asthma, abnormal conditions of the blood, nervousness and other abnormal conditions affecting the

nerves, or abnormal conditions of the prostate gland, as indicated above; 502(b)(2)—the articles failed to bear labels containing an accurate statement of the quality of contents; and 502(e)(2)—the labels of the articles failed to bear the common or usual name of each active ingredient in the articles.

PLEA: Nolo contendere.

DISPOSITION: 1–27–57. $500 fine and probation for 2 years.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 5441 TO 5460

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5447) Seizure contested. Contains opinions of the court.
[2] (5455) Injunction issued.

[2] (5455) Injunction issued.

U. S. GOVERNMENT PRINTING OFFICE: 1959

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE ~~FEDERAL FOOD~~ DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5461–5480

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent and (2) a criminal proceeding terminated upon a plea of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *May 6, 1959.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see Nos. 5463, 5466, 5469; failure to bear a label containing an accurate statement of the quantity of the contents, No. 5463; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5463.

502760—59

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5461–5480

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength and quality differed from that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the proportion of alcohol contained therein; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 502(f)(2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; Section 502(l), the article was, or purported to be, or was represented as, a drug composed partly of chlortetracycline, bacitracin, or any derivative thereof, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503(b)(4), the article was subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and, in another case, the article bore the caution statement quoted above, but the article was not one to which Section 503(b)(1) applies.

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

5461. Coron tablets. (F.D.C. No. 40677. S. No. 53–624 M.)

QUANTITY: 368 btls. at Bellaire, Tex.

SHIPPED: 7–31–57, from St. Louis, Mo., by Keith-Victor Pharmacal Co.

LABEL IN PART: "100 No. 501 Tablets Coron Each Tablet contains: Cobalt Gluconate 25 mg. Ferrous Gluconate 200 mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 2.91 mg. of cobalt (equivalent to 24 mg. of cobalt gluconate) per tablet.

LIBELED: 10–3–57, S. Dist. Tex.

CHARGE: 502(j)—when shipped, the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Dosage: One or two tablets after each

meal"; and 503(b)(4)—the article was a drug subject to 503(b)(1)(B), and the label of the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10–17–57. Consent—claimed by Savage Laboratories, Inc., Bellaire, Tex., and relabeled.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

5462. Pega Palo vine. (F.D.C. No. 40676. S. No. 81–078 M.)

QUANTITY: 9 pieces of vine packaged separately in Pliofilm bags at Washington, D.C.

SHIPPED: 1–15–57, from Chicago, Ill., by A–1 Importing Co.

LABEL IN PART: (Bag) "Pega Palo Vine."

ACCOMPANYING LABELING: Reprints of an article, from the January 1957 issue of "Confidential" magazine, entitled "The Vine That Makes You Virile."

RESULTS OF INVESTIGATION: Examination showed that the article consisted of pieces of fibrous, woody material, 4 to 6 inches in length, which obviously were part of a plant stem.

LIBELED: 10–7–57, Dist. Columbia.

CHARGE: 502(f)(1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use as an aphrodisiac, which was the purpose for which the article was intended; and 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: 11–1–57 and 11–26–57. Default—delivered to the Food and Drug Administration.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

5463. Achromycin capsules. (F.D.C. No. 40513 S. No. 68–277 M.)

QUANTITY: 2 jars containing about 123 capsules at Ridgefield, N.J.

SHIPPED: 3–7–57 and 4–4–57, from New York, N.Y., by Re-Ly-On Drug Co.

RESULTS OF INVESTIGATION: The jars containing the article were shipped unlabeled, and after receipt of the article, one of the jars was labeled with the words "Achromycin V."

LIBELED: 7–15–57, Dist. N.J.

CHARGE: 502(b)(1) and (2)—when shipped, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502(e)(1)—the label of the article failed to bear the common or usual name of the article; 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and the labeling failed to bear the information necessary to exempt the article from such requirement; 502(l)—the article contained tetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to law; and 503(b)(4), the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 9–4–57. Default—destruction.

DRUG FOR VETERINARY USE

5464. Bacitracin ointment (veterinary). (F.D.C. No. 40873. S. No. 78–016 M.)

QUANTITY: 3,216 boxes, each containing 1 syringe, at Lincoln, Nebr.

SHIPPED: 8–16–57, from Inglewood, Calif., by Delta Laboratories.

LABEL IN PART: "Mitox Active Ingredients Per Syringe Bacitracin 3200 Units * * * Veterinarians only * * * Control No. 2175 Expiration Date: Feb. '59."

RESULTS OF INVESTIGATION: Examination showed that the article contained substantially less bacitracin than the label declared.

LIBELED: 10–25–57, Dist. Nebr.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 3,200 units per syringe; and 502(a)—the label statement "Per Syringe Bacitracin 3200 Units" was false and misleading; and 502(l)—the article contained bacitracin, and it was not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: 12–5–57. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

5465. Penicillin. (F.D.C. No. 40934. S. Nos. 76–701/2 M.)

QUANTITY: 47 10-cc. vials and 97 10-cc. vials at Millbury, Mass.

SHIPPED: 3–25–57 and 4–2–57, from Baltimore, Md.

LABEL IN PART: (47-vial lot) "10 cc Crystalline Procaine Penicillin G in Aqueous Suspension 300,000 units per cc"; (97-vial lot) "1,000,000 Units Potassium Penicillin Crystalline 'G'."

RESULTS OF INVESTIGATION: The article was in the possession of a dealer in veterinary supplies, and its labeling did not bear adequate directions for use in the treatment of animals.

LIBELED: 11–4–57, Dist. Mass.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was not intended for use by man, and its label bore the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 12–16–57 and 12–24–57. Default—destruction.

5466. X 100 Cosmetic Solution. (F.D.C. No. 40623. S. No. 41–877 M.)

QUANTITY: 2 1-gal.-size btls., each containing ⅔ of a gal.; 21 btls., each containing 1 oz.; and 10 btls., each containing ½ oz., at Buffalo, N.Y.

SHIPPED: 5–15–57, from Detroit, Mich., by R. Tacon.

LABEL IN PART: (1-gal. btls.) "X 100 Cosmetic Solution Contains 10,000 I.U.△ 1, 3, 5, Estratriene a 3,17 Diol per oz. For External Use Only Distributed by R. Tacon Detroit Mich."

RESULTS OF INVESTIGATION: The article in the 1-oz. and ½-oz. btls. was repacked by the dealer from the 1-gal. btls. described above. The article was employed by the dealer as a hair and scalp treatment, consisting of the application of ½-fluid oz. to the hair and scalp as a single "treatment."

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*See also Nos. 5461, 5463.

Analysis showed that the article consisted of isopropyl alcohol, containing 1.5 mg. of estradiol and 1.8 mg. of alpha-estradiol per fluid ounce.

LIBELED: 8–30–57, W. Dist. N.Y.

CHARGE: 502(e)(2)—when shipped and while held for sale, the label of the article failed to bear the common or usual name of each active ingredient and the proportion of isopropyl alcohol contained in the article; 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and it did not comply with any of the exempting regulations; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its labeling failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10–1–57. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5467. Nutrilite food supplement. (F.D.C. No. 40605. S. No. 30–785 M.)

INFORMATION FILED: 1–6–58, S. Dist. Ohio, against P. E. Lockwood and Harley A. Dudgeon, Kings Creek, Ohio.

ALLEGED VIOLATION: In the course of a sales talk given at Kings Creek, Ohio, on 7–10–57, the defendants made oral representations to the persons present, holding the article out as a treatment for ulcers, rheumatoid arthritis, strokes, high blood pressure, varicose veins, migraine headaches, asthmatic conditions, prostate trouble, eye trouble, and calming the nerves.

LABEL IN PART: (Pkg.) "Nutrilite Junior Food Supplement This package contains multiple vitamin capsules and mineral tablets for use as a dietary food supplement to fortify, or supplement, the diet."

CHARGE: 502(f)(1)—the label of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which it was intended, namely, the diseases, symptoms, and conditions set forth above.

PLEA: Guilty.

DISPOSITION: 1–27–58. Each defendant fined $250.

5468. Oil of wintergreen and aspirin tablets. (F.D.C. No. 40950. S. Nos. 48–754/5 M.)

QUANTITY: 1 55-gal.-size drum containing 4 gals., and 125 doz. 1-oz. btls., 97 doz. 2-oz. btls., 33 doz. 4-oz. btls., and 5 1-gal. jugs of *oil of wintergreen*, and 152 cases, each containing 6 doz. 100-tablet btls., of *aspirin*, at Chicago, Ill., in possession of Dr. Sachs Laboratories.

SHIPPED: Between 7–6–57 and 10–31–57, from Lyndhurst and Newark, N.J., and Norwich, N.Y.

LABEL IN PART: (Btl.) "Oil of Wintergreen (Methyl Salicylate) U.S.P. Synthetic" and "Health-A-Teria Aspirin 5 Grains Each Acetylsalicylic Acid U.S.P. * * * Packed for Health-A-Teria, Inc., Chicago, Illinois."

RESULTS OF INVESTIGATION: The *oil of wintergreen* and the *aspirin tablets* in the above-mentioned btls. were repacked by the consignee from bulk stock shipped as described above.

LIBELED: 11–12–57, N. Dist. Ill.; amended 11–21–57.

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*See also Nos. 5462, 5463, 5465, 5466.

CHARGE: 502(f)(1)—the labeling of the *aspirin tablets*, while held for sale, failed to bear adequate directions for use since, in lieu of a dosage statement for children under 3 years of age, the labeling failed to state that for the 3-year and under age group a physician should be consulted; and 502(f)(2)—the labeling of the *oil of wintergreen* and the *aspirin tablets*, while held for sale, failed to bear warnings against misuse by children since their labelings failed to warn that such articles should be kept out of reach of children.

DISPOSITION: 11–22–57. Consent—claimed by Dr. Sachs Laboratories and relabeled.

5469. **Herb tea.** (F.D.C. No. 40933. S. No. 49–037 M.)

QUANTITY: 133 4-oz. boxes at Chicago, Ill., in possession of W. W. Laboratories.

SHIPPED: During April 1957, from New York, N.Y.

LABEL IN PART: (Box) "Hartz Mountain Brand Herb Tea"; (bulk drum) "Special Cut & Sifted Tea Mixture Formula 68 Containing the following: Alex Senna, Mandrake, Elder Flowers, Aniseed, Fennel Seed, Red Clover Tops, Linden Flowers and Leaves, Dog grass, Sassafras Bark of Root Natural, Uva Ursi."

RESULTS OF INVESTIGATION: The article was shipped, as described above, in bulk drums; and, upon receipt at Chicago, it was repackaged and labeled by the consignee.

LIBELED: 11–7–57, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the box label of the article contained false and misleading representations that the article was an adequate and effective treatment for regulating the stomach, providing perfect health, enabling one to achieve a ripe old age, and eliminating constantly accumulating body poisons; 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient; and 502(f)(2)—the article was essentially a laxative, and its labeling failed to bear adequate warnings against excessive use as a laxative and against use where symptoms of appendicitis are present.

DISPOSITION: 12–5–57. Default—destruction.

DRUGS FOR VETERINARY USE

5470. **C-Ran and Stil-Ran.** (F.D.C. No. 40706. S. Nos. 70–281/2 M.)

QUANTITY: 87 boxes, 6 vials each, of *C-Ran*, and 77 boxes, 5 vials each, of *Stil-Ran*, at Wayne, Pa.

SHIPPED: Between 5–23–57 and 9–12–57, from Baltimore, Md., by Morjac Co.

LABEL IN PART: (Box) "C-Ran * * * Each Ampoule Contains 6 cc. Ascorbic Acid Solution In the Form of Sodium Ascorbate Equal to 2 gm. Ascorbic Acid (40,000) Units Vitamin C" and "Stil-Ran * * * Diethlystilbestrol Solution."

LIBELED: 10–18–57, E. Dist. Pa.

CHARGE: 502(a)—when shipped, the box labels of the articles contained false and misleading representations that the *C-Ran* was effective for overcoming breeding difficulties in cows and that the *Stil-Ran* was effective for treating the condition of retained placenta in cows; and 502(f)(1)—the *Stil-Ran* was a drug which was not safe for animal use except under the supervision of a licensed veterinarian, and the label failed to bear the statement "Caution:

Federal law restricts this drug to sale by or on the order of a licensed veterinarian."

DISPOSITION: 11–18–57. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5471. Digitoxin powder (2 seizure actions). (F.D.C. Nos. 40514, 40515. S. Nos. 62–014 M, 62–019 M.)

QUANTITY: 5 aluminum btls., 2 containing 5 grams and 3 containing 10 grams, at New York, N.Y., and 1 aluminum btl. containing 41.37 grams, at Long Island City, N.Y.

SHIPPED: 11–16–56, from Paris, France, by Labomial L. M.

LABEL IN PART: "Labomial Digitoxin U.S.P."

RESULTS OF INVESTIGATION: Examination showed that the 5-btl. lot of the article contained not more than 84.6 percent digitoxin and that the 1-btl. lot contained not more than 82.8 percent digitoxin.

LIBELED: 7–17–57 and 7–23–57, E. Dist. N.Y., and S. Dist. N.Y.

CHARGE: 501(b)—the strength of the article, when shipped, differed from the standard for digitoxin set forth in the United States Pharmacopeia since it contained less than 90 percent of the labeled amount of digitoxin.

DISPOSITION: 10–17–57 and 10–18–57. Default—destruction.

5472. Digitoxin tablets. (F.D.C. No. 40659. S. No. 68–969 M.)

QUANTITY: 1 drum containing 57,200 tablets at Hempstead, N.Y.

SHIPPED: Between 3–24–53 and 3–7–56, from France.

LABEL IN PART: "Digitoxin 0.1 mg. Pink."

RESULTS OF INVESTIGATION: The shipment consisted of digitoxin powder, which was used in preparing the above-described tablets.

Examination showed that the tablets contained not more than 83 percent of the declared amount of digitoxin.

LIBELED: 10–2–57, E. Dist. N.Y.

CHARGE: 501(b)—while held for sale, the strength of the article differed from the standard for *digitoxin tablets* set forth in the United States Pharmacopeia since the article contained less than 90 percent of the declared amount of digitoxin.

DISPOSITION: 10–25–57. Default—destruction.

5473. Dextro-amphetamine sulfate timed disintegration capsules. (F.D.C. No. 40568. S. No. 62–813 M.)

QUANTITY: 54 100-capsule btls. at Jersey City, N.J.

SHIPPED: 10–30–56, from Long Island City, N.Y., by Nysco Laboratories, Inc.

RESULTS OF INVESTIGATION: Examination showed that the article contained 142 percent of the labeled amount of dextro-amphetamine sulfate and released 64 percent of its dextro-amphetamine sulfate ingredient during the first hour.

LIBELED: 8–15–57, Dist. N.J.

CHARGE: 501(c)—the strength and quality of the article, when shipped, differed from that which it purported to possess since it contained more than

*See also No. 5464.

the labeled amount of dextro-amphetamine sulfate and failed to disintegrate in the manner declared on the label; and 502(a)—the label statements "Dextro-Amphetamine Sulfate 15 Mgm. Timed Disintegration Capsule Each Capsule contains 15 mgm. of Dextro-amphetamine sulfate in a special base that provides for time disintegration of the contents throughout a period of about 6–10 hours. This capsule is equivalent to one tablet of 5 mgm. potency taken three times a day" were false and misleading for a product that contained more than 15 mg. of dextro-amphetamine sulfate per capsule and which did not consist of capsules equivalent to those of 5 mg. potency taken three times a day.

DISPOSITION: 11–29–57. Default—destruction.

5474. Soluble saccharin. (F.D.C. No. 40636. S. No. 68–624 M.)

QUANTITY: 1 45-lb. drum at Brooklyn, N.Y.

SHIPPED: From Holland.

LABEL IN PART: "FHT Saccharine Soluble Granular Made in Holland."

LIBELED: 9–12–57, E. Dist. N.Y.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for soluble saccharin set forth in the United States Pharmacopeia since the article exceeded the heavy metals limit of 20 parts per million.

DISPOSITION: 10–18–57. Default—destruction.

5475. Prophylactics. (F.D.C. No. 40576. S. Nos. 44–343/4 M, 44–356/7 M.)

QUANTITY: 27 ctns., each containing 48 pkgs. and each pkg. containing 3 units, at Little Rock, Ark.

SHIPPED: 5–7–57 and 5–27–57, from Atlanta, Ga., by W. H. Reed & Co.

LABEL IN PART: (Pkg.) "Golden Pheasant * * * Prophylactics * * * One Fourth Dozen"; (individual foil wrapped unit) "One Lubricated Golden Pheasant Prophylactic Insist on the Genuine Mfgd. in W. Germany Packed by W. H. Reed & Co., Atlanta, Ga."

RESULTS OF INVESTIGATION: Examination showed that the article was defective in that it contained holes.

LIBELED: 8–22–57, E. Dist. Ark.

CHARGE: 501(c)—the quality of the article fell below that which it purported to possess when shipped; and 502(a)—the label statement "Prophylactics" was false and misleading as applied to a product containing holes.

DISPOSITION: 10–1–57. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

5476. Invertose. (F.D.C. No. 40937. S. No. 78–645 M.)

QUANTITY: 3 ctns., 12 btls. each, at Wichita, Kans.

SHIPPED: Between 3–18–57 and 9–28–57, from Lincoln, Nebr., by Norden Laboratories.

LABEL IN PART: (Btl.) "Norden 500 cc Invertose A source of readily assimilable carbohydrate for parenteral use."

RESULTS OF INVESTIGATION: Examination showed that the article was invert sugar.

*See also Nos. 5464, 5469, 5470, 5473, 5475.

LIBELED: 11–7–57, Dist. Kans.

CHARGE: 502(a)—when shipped, the label of the article contained false and misleading representations that the article was an effective and adequate treatment for milk fever.

DISPOSITION: 12–19–57. Default—destruction.

5477. Cabbex. (F.D.C. No. 40663. S. No. 78–008 M.)

QUANTITY: 29 btls. at Omaha, Nebr., in possession of Vitamin Stores, Inc.

SHIPPED: 4–9–57, from Huntington Park, Calif.

LABEL IN PART: "One Pound Guardian Concentrate Cabbex Cabbage Powder For Cabbage Juice * * * As a supplementary source of the nutrients in cabbage take four teaspoonsful daily."

ACCOMPANYING LABELING: Window placard reading: "Ulcers? Try Cabbex Cabbage Juice Powder $3.98."

RESULTS OF INVESTIGATION: The article was shipped as described above in 30-lb. bulk drums, and after receipt by the consignee, it was repacked into bottles.

LIBELED: 9–27–57, Dist. Nebr.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an effective treatment for ulcers.

DISPOSITION: 10–25–57. Default—destruction.

5478. Dr. Bronner's Calcium & Phosphorus, Vegetable. (F.D.C. No. 40918. S. Nos. 73–243/4 M.)

QUANTITY: 22 2-oz. btls. and 5 1½-oz. btls. at Denver, Colo.

SHIPPED: Between 1–10–57 and 6–19–57, from Los Angeles, Calif., by Dr. E. H. Bronner & Associates.

LABEL IN PART: "Dr. Bronner's Calcium & Phosphorus, Vegetable made from vegetable calcium, rosehips, rice polish, dulse, barley, yeast & malt."

ACCOMPANYING LABELING: Circular, reading in part, "Dr. Bronner's Calcium & Phosphorus, Vegetable."

LIBELED: 10–30–57, Dist. Colo.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that fluoridation is wrong; that the right way to prevent tooth decay is with organic-vegetable and oceanic calcium food; and that the article was adequate and effective for preventing tooth decay, polio, bone brittleness, and loose dentures.

DISPOSITION: 12–31–57. Default—destruction.

5479. Grapefruit powder. (F.D.C. No. 40523. S. No. 57–929 M.)

QUANTITY: 1 25-lb. tin and a number of 8-oz. jars at Orange City, Fla., in possession of Wolf Laboratories.

SHIPPED: On an unknown date, from Huntington Park, Calif.

LABEL IN PART: (Jar) "Whole Powdered Grapefruit."

RESULTS OF INVESTIGATION: The article in the jars had been repacked from bulk stock which was shipped as described above.

LIBELED: 7–22–57, S. Dist. Fla.

CHARGE: 502(a)—the labeling of the article, while held for sale, namely, the label of the repackaged article, contained false and misleading representations that the article was an adequate and effective treatment for diabetes; that the article was effective in the prevention and treatment of high blood pressure and hardening of the arteries; that it would keep the blood cells and body tissues youthful; and that it would enable the body to resist infection.

DISPOSITION: On 8–12–57, John Wolf, claimant, filed exceptions to the libel; and, on 10–3–57, the exceptions were denied. On 4–23–58, on motion of both parties to the libel action, judgment of condemnation was entered and the court ordered that the product be destroyed.

5480. 3N liniment. (F.D.C. No. 40133. S. No. 57–190 M.)

QUANTITY: 984 4-oz. btls. and 1 5-gal. btl. at Cedartown, Ga., in possession of Colston's Sales Co.

SHIPPED: 6–26–56 and 2–13–57, from Chattanooga, Tenn.

LABEL IN PART: (4-oz. btl.) "3N Liniment * * * Active Ingredients: Camphor, Capsicum, Citronella, Cajeput, Spikenard, Castor Oil, Alkanet, Isopropyl Alcohol 80–85 percent * * * 4 Fluid Ounces Price $1.35 Distributed by Colston's Sales Co., 230 3rd Street, Cedartown, Georgia."

ACCOMPANYING LABELING: Leaflets entitled "Directions For The Use of 3N Liniment" and "3N Liniment Reg. U.S. Pat. Office."

RESULTS OF INVESTIGATION: The leaflets were printed at the direction of the dealer.

LIBELED: 4–10–57, N. Dist. Ga.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for rheumatism, arthritis, neuritis, lumbago, deep pains, and "other things where a pain or germ killer is needed."

DISPOSITION: 10–28–57. Consent—claimed by Colston's Sales Co. and relabeled.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 5461 TO 5480

PRODUCTS

[1] (5479) Seizure contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5479) Seizure contested.

U. S. GOVERNMENT PRINTING OFFICE: 1959

D.D.N.J., F.D.C. 5481–5500 Issued June 1959

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5481–5500

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; (2) criminal proceedings terminated upon pleas of guilty; and (3) injunction proceedings in which decrees of injunction were entered with the consent of the parties, or after default. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., May 27, 1959.

CONTENTS*

*For presence of a habit-forming substance without warning statement, see No. 5485; omission of, or unsatisfactory, ingredients statements, Nos. 5485, 5486; sale under name of another drug, No. 5481; failure to bear a label containing an accurate statement of the quantity of the contents, No. 5486; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 5486, 5487.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5481–5500

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength and quality differed from that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the quantity, kind, and proportion of alcohol, and the name, and quantity or proportion of atropine, hyoscine, and hyoscyamine contained therein; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 502(g), the article purported to be a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and it was not packaged as prescribed therein; Section 502(i)(3), the article was a drug offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in the labeling; Section 502(l)(2), the article was, or purported to be, or was represented as, a drug composed wholly or partly of penicillin; and it was from a batch with respect to which a certificate issued pursuant to Section 507 was not in effect; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

5481. Castor oil and hydrogen peroxide solution. (F.D.C. No. 40474. S. Nos. 24–038 M, 50–722 M, 50–821 M.)

INFORMATION FILED: 2–10–58, S. Dist. Calif., against Norton Chemical Co., Inc., t/a Norton Products Co., Los Angeles, Calif.

ALLEGED VIOLATION: During the year of 1956, while a quantity of turpentine was being held for sale at Los Angeles, Calif., after shipment in interstate commerce, the defendant caused the turpentine to be repacked into bottles labeled,

in part, as "Norco Castor Oil," which act resulted in the article being adulterated and misbranded as described below.

In addition, between 1–15–57 and 1–24–57, the defendant caused to be introduced into interstate commerce, at Los Angeles, Calif., for delivery to Phoenix, Ariz., a quantity of an article labeled, in part, "Enterprise Solution of Hydrogen Peroxide U.S.P. 10 Volume ¼ Lb. (4 Oz. Av.) Enterprise Drug & Chemical Company Los Angeles, Calif.," which was adulterated as described below.

CHARGE: *Castor oil.* 501(d)(2)—turpentine had been substituted for *castor oil*, which the article was represented to be; 502(a)—the label statement "Castor Oil" was false and misleading; 502(i)(3)—the article was turpentine, and it was offered for sale under the name of another drug, namely, *castor oil;* and 502(j)—the article was dangerous to health when used in the dosage prescribed, recommended, and suggested in its labeling, namely, "Dose: Children, one to two teaspoonfuls. Adults, one to two tablespoonfuls."

Hydrogen peroxide solution. 501(b)—the quality and purity of the article fell below the standard for *hydrogen peroxide solution* set forth in the United States Pharmacopeia since the article contained isopropyl alcohol, which is not permitted in such standard.

PLEA: Guilty.

DISPOSITION: 4–21–58. $1,500 fine.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5482. Royal jelly capsules and royal jelly cream (2 seizure actions). (F.D.C. Nos. 41270, 41271. S. Nos. 73–114/7 M.)

QUANTITY: 71 btls., each containing 18 50-mg. capsules; 50 btls., each containing 60 50-mg. capsules; 24 btls., each containing 100 50-mg. capsules; 41 btls., each containing 15 75-mg. capsules; 30 btls., each containing 30 75-mg. capsules; 19 btls., each containing 15 125-mg. capsules; and 20 btls., each containing 30 125-mg. capsules, of *royal jelly;* and 43 1-oz. jars and 16 2-oz. jars of *royal jelly cream*, at Denver, Colo.

SHIPPED: Between 8–30–57 and 10–24–57, from Bayonne, N.J., by Continental Honey Products, Inc.

LABEL IN PART: (Btl.) "Imperial Royal Jelly Capsules * * * Continental Honey Products, Inc., Dist. N.Y."; (jar) "Imperial Royal Jelly Cream Continental Honey Products, Inc., Dist. N.Y." and "Imperial Royal Jelly Cream Queen Bee Royal Jelly and Lecithin."

ACCOMPANYING LABELING: Circulars entitled "Facing New Horizons With Imperial Royal Jelly."

LIBELED: 12–12–57, Dist. Colo.

CHARGE: 502(a)—the labeling accompanying the articles, when shipped, contained false and misleading representations that the articles would cure the ill, aid in the treatment of cancer, lengthen life, be beneficial in sexual deficiencies and ailments, be effective in the treatment of diseases of children, and increase intellectual activity; and that they were effective in treating liver ailments, arthritis, leukemia, and ulcers; and 505(a)—the articles were new drugs within the meaning of the law, and applications filed pursuant to the law were not effective with respect to the drugs.

DISPOSITION: 2–12–58. Default—a portion of the articles was delivered to the Food and Drug Administration, and the remainder was destroyed.

5483. Vitamin B_{12} injection. (F.D.C. No. 40987. S. No. 75–640 M.)

QUANTITY: 87 vials at Los Angeles, Calif.

SHIPPED: 10–22–57 and 10–31–57, from Philadelphia, Pa., by Philadelphia Ampoule Laboratories.

LABEL IN PART: "10 cc * * * Multiple Dose Vial Brown Balamin-1000 * * * For Intravenous or Intramuscular Use Each cc contains: 1000 Micrograms Vitamin B_{12} Crystalline U.S.P. Preservative: Benzyl Alcohol 1.5% This product made with Isotonic Sodium Chloride Solution USP."

RESULTS OF INVESTIGATION: Examination showed that each cubic centimeter of the article contained 1,027 micrograms of cyanocobalamin (vitamin B_{12}), 7.46 milligrams of sodium chloride, and a substantial amount of unidentified dissolved material, the presence of which was not stated on the label.

LIBELED: 12–13–57, S. Dist. Calif.

CHARGE: 501(b)—the article purported to be and was represented as "Cyanocobalamin Injection," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and the quality and purity of the article, when shipped, fell below the standard set forth in the compendium since the article contained a substantial amount of unidentified dissolved material, the presence of which is not permitted under the terms of the United States Pharmacopeia monograph for cyanocobalamin injection; and 505(a)—the article, because of the presence of unidentified dissolved material, was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective.

DISPOSITION: 1–20–58. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

5484. Elixir Sedalet and penicillin tablets with sulfonamides. F.D.C. No. 40655. S. Nos. 67–551/3 M, 67–557 M.)

QUANTITY: 720 btls. (lot No. 5881–VR), 45 btls. (lot No. 7264), and 45 btls. (lot No. 7308) of *elixir Sedalet*, and 6 ctns., 24 btls. each, of *penicillin tablets with sulfonamides*, at Falls Church, Va.

SHIPPED: 7–15–55, from Bethesda, Md., by Marshall Laboratories, Inc.

LABEL IN PART: (Btls.) "Marshall One Pint (473 cc) Elixir Sedalet Each Teaspoonful Contains: Phenobarbital ¼ gr. (16 mg.) Thiamin Chloride 5 mg." and "Pendiamer '200' Brand of Penicillin Tablets with Sulfonamides * * * Each tablet contains: Penicillin G Potassium Crystalline 200,000 U * * * Lot #5883."

RESULTS OF INVESTIGATION: Examination showed that the *elixir Sedalet* contained (lot No. 5881–VR) 128 percent of the declared amount of phenobarbital and (lot Nos. 7264 and 7308) less than 80 percent of the declared amount of thiamine chloride, and that the *penicillin tablets with sulfonamides* contained 69.5 percent of the declared amount of penicillin and were labeled with the expiration date "Feb. 1956."

LIBELED: 9–19–57, E. Dist. Va.

CHARGE: *Elixir Sedalet.* 501(c)—when shipped, the strength of the article differed from that which it was represented to possess since the article (lot No. 5881–VR) contained more than ¼ grain of phenobarbital per teaspoonful and (lot Nos. 7264 and 7308) contained less than 5 mg. of thiamine chloride

per teaspoonful; and 502(a)—the label statements (lot No. 5881–VR) "Each Teaspoonful Contains * * * Phenobarbital ¼ gr." and (lot Nos. 7264 and 7308) "Each Teaspoonful Contains * * * Thiamin Chloride 5 mg." were false and misleading.

Penicillin tablets with sulfonamides. 501 (c)—when shipped, the strength of the article differed from that which it was represented to possess since it contained less than 200,000 units of penicillin G potassium crystalline per tablet; 502(a)—the label statement "Each tablet contains: Penicillin G Potassium Crystalline 200,000 U" was false and misleading; and 502(l) (2)—the article purported to be and was represented as a drug composed in part of penicillin and was from a batch for which a certificate issued in accordance with regulations was not in effect.

DISPOSITION: 1–14–58. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5485. Elixir Albephen and elixir Merbutal. (F.D.C. No. 40468. S. Nos. 67–474 M, 67–478 M.)

INFORMATION FILED: 2–5–58, Dist. Md., against Meredyth Co., a partnership, Silver Spring, Md., and Irwin T. Sealfon, a partner.

ALLEGED VIOLATION: Between 9–23–55 and 5–16–57, the defendants caused a quantity of *elixir Albephen* in 1-gal. btls. to be repacked into 1-pt. btls. and a quantity of *elixir Merbutal* in 1-gal. btls. to be repacked into 1-oz. btls., which acts of repacking resulted in the repacked articles being misbranded while held for sale after shipment in interstate commerce.

LABEL IN PART: (Btl.) "One Pint Elixir Albephen Each Ounce Contains: D. Amphetamine Sulfate 15 mg. Thiamin HCL 30 mg. Riboflavin 2.7 mg. Niacin 40 mg. Alcohol 10% Distributors The Meredyth Company Washington, D.C. The M Co." and "Physicians Sample One Ounce Elixir Merbutal Each 5cc (One teaspoonful) contains: Sodium-5-ethyl-secondary butyl barbiturate 3 grs. (brand of Butabarbital sodium) Distributors The Meredyth Company Washington, D.C."

CHARGE: *Elixir Albephen.* 502 (a)—the label statement "Each Ounce Contains: D. Amphetamine Sulfate 15 mg. Thiamin HCL 30 mg. Riboflavin 2.7 mg. Niacin 40 mg. Alcohol 10%" was false and misleading since each ounce of the article contained no d. amphetamine sulfate, no thiamine HCl, no riboflavin, and no niacin, and contained more than 10 percent of alcohol; 502(d)—the article contained phenobarbital, a derivative of barbituric acid, which had been found to be, and by regulations designated as, habit forming, and the label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; 502(e)(2)—the label of the article failed to bear the common or usual name of the active ingredient, phenobarbital, the name, and quantity or proportion of hyoscyamine sulfate, atropine sulfate, and hyoscine hydrobromide, and the quantity, kind, and proportion of alcohol contained in the article; and 503(b)(4)—the article was a drug subject to 503(b)(1), and the label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Elixir Merbutal. 502(a)—the label statement "Each 5cc (one teaspoonful) contains: Sodium-5-ethyl-secondary butyl barbiturate 3 grs. (brand of butabarbital sodium)" was false and misleading in that each 5cc of the drug

contained less than 3 grs. of sodium-5-ethyl-secondary butyl barbiturate (brand of butabarbital sodium); 502(d)—the article contained butabarbital sodium, a derivative of barbituric acid, which had been found to be, and by regulations designated as, habit forming; and the label failed to bear the quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

PLEA: Guilty.

DISPOSITION: 6–27–58. The sentence against the partnership was suspended, and a fine of $1,000, plus costs, was imposed against the individual.

5486. **Arben capsules.** (F.D.C. No. 40531. S. Nos. 65–351/5 M.)

QUANTITY: 1 bag containing 3,200 capsules, and 83 42-capsule boxes at Youngstown, Ohio, in possession of Dr. R. J. Turner and Fred C. Bennett.

SHIPPED: Between 12–31–56 and 4–18–57, from Miami Beach, Fla., by Arthur Bennett.

RESULTS OF INVESTIGATION: The capsules in the boxes had been shipped in bulk, and after receipt by the consignee, were repackaged. Various lots of the capsules, when shipped, were labeled as containing amphetamine sulfate in amounts ranging from 1.2 mg. to 5 mg. per capsule.

Examination showed that the capsules contained from 164 percent to 204 percent of the declared amount of amphetamine sulfate per capsule.

LIBELED: 7–24–57, N. Dist. Ohio.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess.

502(b)(1) and (2)—while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502(e)(2)—the label of the article, while held for sale, failed to bear the common or usual name of each active ingredient; and 503(b)(4)—the article was a drug subject to 503(b)(1), and, while held for sale, its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10–23–57. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

5487. **Theraphone device and methyl salicylate ointment.** (Inj. No. 315.)

COMPLAINT FOR INJUNCTION FILED: 10–10–57, N. Dist. Ill., against Neo-Sound Corp. of America, Wheeling, Ill., and William Dunkler, t/a Wm. Dunkler Laboratories, Chicago, Ill.

ACCOMPANYING LABELING: Leaflets entitled "Theraphone the Neo-Sound Instrument that can help you"; typed sheet bearing the Neo-Sound Corp. of America letterhead and a heading containing the words "Here's what Theraphone owners say"; leaflets entitled "Instructions for the Use of the Theraphone," "New Professional Model Theraphone . . . Dear Doctor," and "Letters of Satisfaction from Hospitals, Clinics and Doctors who have Used the Neo-Sound Instrument for some time"; form letter headed "Dear Doctor"; general "Out-Lay" chart showing location of areas of the human body where treatments should be applied; leaflet headed "Dear Doctor"; sheet headed "Direc-

tions"; pamphlets entitled "Naturopathic Medical Journal * * * of the Florida Naturopathic Physicians' Association Inc. Fall Issue Vol. 2 No. 1" and "Naturopathic Medical Journal * * * of the Florida Naturopathic Physicians' Association Inc. Winter Issue Vol. 2 No. 2"; and a sheet entitled "Selling Points for the Sale of the Professional Model Theraphone."

RESULTS OF INVESTIGATION: The device consisted of 2 models. One model was designated as a professional model, which was encased in a cylindrical-shaped, polished aluminum unit measuring approximately 7½ inches long by 1¾ inches in diameter and which had three sound heads for varying degrees of penetration and a push-button micro switch. The second model was similar to the professional model, but it was smaller in size and was encased in a plastic unit. Both models were operated by house current and had a rubber electric cord attached, with a common male plug. Each model purported to be an electrically operated massage vibrator which would produce sound waves of various frequencies.

CHARGE: The complaint charged that the defendants were violating the Act by causing the introduction and delivery for introduction into interstate commerce of *methyl salicylate ointment* and the *Theraphone device* which were misbranded as follows:

Methyl salicylate ointment. 502(b)(1)—the label of the article failed to bear the name and place of business of the manufacturer, packer, or distributor; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use, in that the labeling failed to bear any directions for use.

Theraphone device. 502(a)—the labeling of the article when viewed as a whole, as well as through specific claims, and in the setting in which it was presented, contained false and misleading representations that the action of the article was markedly different from the action of ordinary massage vibrators and that the article was adequate and effective in the treatment of arteriosclerosis, arthritis, muscular rheumatism, gout, inflammation of the muscles, gallbladder inflammation, gastritis, constipation, neuritis, migraine headache, facial palsy, neuralgia, sciatica, bursitis, muscular atrophy, hemorrhage, menstrual cramps, tonsillitis, sore throat, sinus conditions, head colds, cystitis, urethritis, prostatitis, aching feet, congestion, impaired blood circulation, and all ailments of an inflammatory or circulatory nature.

The complaint charged further that if the defendants were forced by injunction to refrain from using the above labeling on interstate shipments of the device, the defendants would not discontinue interstate distribution of the device but would, unless enjoined, continue to ship the device in interstate commerce without labeling stating the conditions and purposes for which the device was intended, namely, for the treatment of the above-mentioned diseases and conditions. In such case, the device would be misbranded within the meaning of 502(f)(1), in that its labeling would fail to bear adequate directions for use, because of the omission from the labeling of statements of the conditions and purposes for which the device was intended.

The complaint alleged also that the defendants had been warned by the Food and Drug Administration through establishment inspections made on March 16 and 18, September 16, and October 13, 1955, and June 17 and 19, 1957; by letters dated June 7, 1955, and February 8 and June 26, 1956; by a conference held on June 16, 1955; and by hearings held on January 19 and February 9, 1956, pursuant to Section 305, that the device was misbranded by reason of its false and misleading labeling, and that despite such warnings,

the defendants continued to introduce and deliver for introduction into interstate commerce the misbranded device.

DISPOSITION: 12–27–57. The defendants having consented, the court entered a decree of permanent injunction enjoining them against the acts complained of.

5488. Schramm's massage brushes, Diamix devices, and Model B–50 generators and B–50 cabinets. (F.D.C. No. 41301. S. Nos. 72–295/7 M.)

QUANTITY: 54 Schramm's *massage brushes*, 3 *Diamix devices*, and 4 *Model B–50 generators* and 5 *B–50 cabinets* at Hinsdale, Ill., in possession of Midwest Imports.

SHIPPED: Between 10–10–55 and 9–17–57, from Germany.

ACCOMPANYING LABELING: (Schramm's massage brush) leaflets entitled "Schramm's Massage Brush Ideal M.I."; (Diamix device) reference sheets entitled "Illinois Masonic Hospital Association," leaflets entitled "Diamix The Universal Apparatus," and a number of sheets entitled "Indications for the Helio-Therapy with Diamix"; and (Model B–50 generator and B–50 cabinet) booklets entitled "Praktische Erfahrungen," leaflets entitled "Statement—Alexian Brothers Hospital," and reprints entitled "Infrared Radiation Baths Protect Your Health."

RESULTS OF INVESTIGATION: Examination showed that the *Schramm's massage brush* was a rubber brush with a varnished wooden handle (de luxe model) or with a plain wooden handle (economy model); that the *Diamix device* was a radiant lamp with a wire-wound infraheat element and 5 interchangeable bulbs of different colors for ultraviolet, neon, red, blue, and green radiation, and with a fixed infrared emitter; and that the device, consisting of the *Model B–50 generator* and *B–50 cabinet*, comprised a cabinet, heater, and stool. The cabinet was covered with imitation leather, was heat and waterproof, with a steel spring inlayer, and was lined with reflective material. It had a top closure and floor cover of imitation leather and a thermometer for reading temperature. The cabinet weighed about 8 lbs., was 42 inches high when set up, and had a 10-inch radius when rolled. The heating unit was a nonglowing generator of rustproof metal, operated by an off-on switch inside the cabinet. The stool had a seat of plastic upholstery, was 12 inches in diameter, and had black, plastic-tipped legs.

The accompanying labeling of the articles, consisting of the above-mentioned booklets, was obtained by the consignee from Germany, and the other items of accompanying labeling were printed locally for the consignee.

LIBELED: 12–26–57, N. Dist. Ill.

CHARGE: *Schramm's massage brush.* 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article would be effective in the treatment and prevention of degenerative diseases, such as heart affections, rheumatism, sciatica, and circulation troubles; that it would stimulate the inner organism; that it would expedite skin regeneration; that it would help procure youthful complexion; that it would prevent debilitation of the back; and that it would strengthen nerve fibers of the spine.

Diamix device. 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the colors of the visible spectrum (neon, red, blue, and green), which were provided by the article, had therapeutic value, and that those colors, together with the ultra-

violet radiation provided by the article, were adequate and effective in the treatment for (ultraviolet) various types of dermatitis, eczema, psoriasis, scalp diseases, rachitis, scrofulosis, glandular disturbances, and "epidimytis"; (red) in all cases where hyperthermia is indicated—in place of diathermy, acute and subacute inflamed processes, rheumatism, lumbago, sciatica, neuralgia, neuritis; affections of the middle ear, irritations of frontal and maxillary sinus, rhinitis, gallbladder infections, and gynecological disturbances; (blue) for the relief and abolishment of pains, for bactericidal effect in cases of: furunculosis, infected surface wounds, infections of the middle ear, sinus, and jaws; paradentitis, all types of burns, after X-ray treatments, necrosis, and frostbites; (neon) in all chronic conditions of rheumatic nature, rheumatism, sciatica, arthritis deformans, pyelitis, cystitis, gynecological disorders, "pleuritism," and phlebitis; and (green) various respiratory disorders, small and large bronchial infections, and virus flu's.

Model B–50 generator and *B–50 cabinet.* 502(a)—while held for sale, the accompanying labeling of the articles contained false and misleading representations that the articles were an adequate and effective treatment for rheumatoid arthritis, diseases of the heart, blood vessels, kidney, bladder, gallbladder, neuralgia, nervous disorders, respiratory infections, arteriosclerosis, grippe, eczema and dermatologic disorders, goiter, pneumonia, bronchial asthma, pleurisy, chronic constipation, phantom limb syndrome, high blood pressure, ankylosis, spondylitis, stomach disorders, menopausal difficulties, "Parkinson," diabetes, insomnia, obesity and other disease, and catarrhal disease; and that the articles would have a beneficial effect on the vegetative nervous system, increase circulation, intensify activity of the endocrine glands, accelerate metabolic processes, multiply white blood corpuscles, detoxicate the entire body, and kill disease germs; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use, and the articles were not entitled to any exemption from such requirement since the articles, because of their potentiality for harmful effect, method of use, and collateral measures necessary for their use, were not safe for use except under the supervision of a practitioner licensed by law to direct the use of such articles; and their labels failed to bear the statement "Caution: Federal law restricts this device to sale by or on the order of a _____," the blank to be filled with the designation of any practitioner licensed by the law of the State in which he practices, to use or order the use of the device.

DISPOSITION: 1–22–58. Consent—claimed by Karl Hausner, t/a Midwest Imports, and relabeled.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5489. Dextro-amphetamine sulfate timed disintegration capsules. (F.D.C. No. 40530. S. No. 69–500 M.)

QUANTITY: 28,500 capsules in bottles at Philadelphia, Pa.

SHIPPED: 1–28–57, from Brooklyn, N.Y., by Robin Pharmacal Corp.

LABEL IN PART: (Btl.) "500 T.D.C. (Timed Disintegration Capsule) Dextro-Amphetamine Sulfate 15 mgm. Each capsule contains 15 mgm. of Dextro-amphetamine sulfate in a special base that provides for timed disintegration

*See also Nos. 5481, 5483, 5484, 5486.

of the contents throughout a period of about 6–10 hours. This capsule is equivalent to one tablet of 5 mgm. potency taken three times a day. * * * Warning * * * Caution: Federal law prohibits * * * Supplied by Physicians Drug & Supply Co. Philadelphia, Pa."

LIBELED: 7–24–57, E. Dist. Pa.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it was represented to possess since the active ingredient was not gradually released over a 6–10 hour period but instead was released in a much shorter time; and 502(a)—the label statements which represented that the active ingredient was gradually released over a 6–10 hour period and that 1 capsule of the article was equivalent to 1 tablet of 5 mgm. potency taken three times a day were false and misleading as applied to the article, since the active ingredient was released in less than a 6-hour period and since 1 capsule of the article was not equivalent to 1 tablet of 5 mgm. potency taken three times a day.

DISPOSITION: 9–12–57. Default—destruction.

5490. Digitoxin tablets. (F.D.C. No. 40298. S. Nos. 68–386/88 M, 68–390 M, 68–392 M.)

QUANTITY: 15 ctns., 12 100-tablet btls. each; 1 drum of 66,400 tablets and 1 drum of 99,800 tablets; 13,500 tablets in 100-tablet btls.; and 1 ctn. containing 19 1,000-tablet btls., at New York, N.Y., in possession of Park Drug Co., Inc.

SHIPPED: The tablets were prepared from digitoxin powder shipped between Oct. 1954 and Nov. 1956, from Paris, France.

LABEL IN PART: (Btls. and drums) "Digitoxin Tablets * * * 0.1 mg. [or "0.2 mg."]."

RESULTS OF INVESTIGATION: Examination showed that the tablets contained not more than 82.6 percent of the declared amount of digitoxin.

LIBELED: 6–5–57, S. Dist. N.Y.

CHARGE: 501(b)—the strength of the article, while held for sale, differed from the standard for digitoxin tablets set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin, the minimum permitted by the standard.

DISPOSITION: 10–17–57. Default—destruction.

5491. Digitoxin tablets. (F.D.C. No. 40202. S. Nos. 62–918/9 M.)

QUANTITY: 58,400 tablets in 100-tablet btls. and 227,000 tablets in 1,000-tablet btls. at South Hackensack, N.J.

SHIPPED: Digitoxin powder was shipped on 5–7–56, from New York, N.Y.

LABEL IN PART: (Btls.) "Digitoxin U.S.P. 0.1 mg."

RESULTS OF INVESTIGATION: The tablets were prepared from the digitoxin powder shipped as described above.

Examination showed that the 58,400-tablet lot and the 227,000-tablet lot contained not more than 79.2 percent and 82.3 percent, respectively, of the declared amount of digitoxin.

LIBELED: 5–15–57, Dist. N.J.

CHARGE: 501(b)—the strength of the article, while held for sale, differed from the standard for digitoxin tablets set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin.

DISPOSITION: 9–19–57. Default—destruction.

5492. Rythrogen. (F.D.C. No. 40398. S. No. 53–744 M.)

QUANTITY: 93 10-cc. vials at Dallas, Tex.

SHIPPED: 4–4–57 and 6–13–57, from Saratoga Springs, N.Y., by G. F. Harvey Co.

RESULTS OF INVESTIGATION: Examination showed that the article contained less than the declared amount of thiamine hydrochloride.

LIBELED: 8–1–57, N. Dist. Tex.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it was represented to possess, namely, 4.5 mg. per cubic centimeter of thiamine hydrochloride; and 502(a)—the label statement "Each cc Contains * * * Thiamine Hydrochloride 4.5 mg." was false and misleading.

DISPOSITION: 9–3–57. Default—destruction.

5493. Pep-Ti-Kon. (F.D.C. No. 40410. S. No. 44–189 M.)

QUANTITY: 96 8-oz. btls. at Forrest City, Ark.

SHIPPED: 5–2–57, from Memphis, Tenn., by Berjon Co.

LABEL IN PART: "Blood-building Tonic * * * Pep-Ti-Kon."

RESULTS OF INVESTIGATION: Examination showed that the article contained 65 percent of the labeled amount of riboflavin.

LIBELED: 8–9–57, E. Dist. Ark.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it was represented to possess, namely, 3.0 mg. per fluid ounce; and 502(a)—the label statement "Each fluid ounce provides: * * * vitamin B_2 (Riboflavin) 3.0 Mg." was false and misleading.

DISPOSITION: 9–11–57. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

5494. Nulsar. (Inj. No. 309.)

COMPLAINT FOR INJUNCTION FILED: 4–25–57, E. Dist. Mich., against Appletone Drugs, Inc., and Appletone Drug Laboratories, Inc., of Detroit, Mich., and Samuel Krone, president of the corporations and owner of the businesses operated under the names of Appletone Drugs and Nulsar Drug Laboratories, at Detroit, Mich.

LABEL IN PART: (Ctn.) "Nulsar-6 Special Tablets * * * For each full ounce of the enclosed product, the following ingredients are included: Powdered extracts of cattle organs in the following manner: Brain substance 2 grains Suprarenal substance ½ grain Desiccated liver 20 grains Hemoglobin 5 grains Gastric mucin 4 grains also: Ferrous gluconate 1 grain Pure dehydrated cream and milk containing not less than 53% up to 60% milk fat at the time of manufacture 325 grains Powdered cocoa, flavoring, sucrose, preservative, added."

*See also Nos. 5481, 5482, 5484, 5485, 5487–5489, 5492, 5493.

ACCOMPANYING LABELING: Leaflet headed "THE 'NULSAR-6' STORY To You—With an Ulcer problem—Here is wonderful news"; two sheets consisting of a reprint of a portion of an article published in the July 1956 issue of Confidential Magazine and headed "The end of 20,000,000 American bellyaches * * * an amazing new pill that banishes ulcers without drugs or surgery!" and a sheet headed "Nulsar Drug Laboratories, 18444 Sorrento Avenue, Detroit 35, Michigan—Dear Doctor: You have probably seen the enclosed publicity given to the imported tablets that are being taken for ulcers."

CHARGE: The complaint alleged that the defendants were violating the Act by causing the introduction and delivery for introduction into interstate commerce of the drug *Nulsar* which was misbranded as follows:

502(a)—the labeling of the article, including the designation "Nulsar," the statement "'Nulsar-6' Tablets are most helpful in stomach and duodenum conditions that need a highly absorbent coating over any painful lesions or areas," appearing on the carton, and the statements in the accompanying labeling, were false and misleading since such labeling, when viewed in the setting in which used, represented and suggested that the article was adequate and effective in the treatment of ulcers in humans and in the treatment of stomach and duodenum conditions that need a highly absorbent coating over painful lesions and areas, whereas the article was not adequate and effective in the treatment of such conditions.

The complaint alleged also that if the defendants were forced by an injunction to refrain from using the above-mentioned labeling on interstate shipments of the article, the defendants would not discontinue interstate distribution of the article but would, unless enjoined, continue to ship the article in interstate commerce without labeling stating the conditions and purposes for which the article was intended; and that in such case, the article would be misbranded under 502(f)(1) in that its labeling would fail to bear adequate directions for use, because of the omission from the labeling of statements of the conditions and purposes for which the article was intended.

DISPOSITION: On 4–26–57, a temporary restraining order was issued against the defendants. On 5–14–57, the defendants having consented, a decree of permanent injunction was entered enjoining the defendants against using the names, "Nulsar," "'Nulsar-6'" "Nulsar Drug Laboratories," or "Nulsar Products Company," in any capacity in interstate commerce, and against introducing and delivering for introduction into interstate commerce the article of drug designated as "Nulsar," and against causing the introduction or delivery for introduction into interstate commerce of *Nulsar* or any article of similar composition which—

(1) is accompanied by the above-mentioned accompanying labeling, or any written, printed, or graphic matter substantially to the same effect;

(2) bears or is accompanied by written, printed, or graphic matter which suggests use of the article in the treatment of ulcers, or which contains the false and misleading representations referred to above, or which is otherwise false and misleading; or

(3) does not have labeling that clearly states every disease, condition, symptom, and purpose for which the article is intended to be used and for which it is represented by any means to the public.

5495. Smylax tablets, Smylax tonic, and Ardine tablets. (Inj. No. 313.)

COMPLAINT FOR INJUNCTION FILED: 6–25–57, N. Dist. Ill., against Alexander P. McArthur, t/a Smylax Co. and Ardine Co., Chicago, Ill.

ACCOMPANYING LABELING: (Smylax tablets and Smylax tonic) Leaflets entitled "Smylax Tonic Good For Many Ailments * * * Why Grow Old? Be Ageless—Defeat Time Forget The Calendar" and "A Hidden Secret Disclosed"; (Ardine tablets) leaflets entitled "Ardine For Feminine Hygiene and Health" and "Ardine For Ideal Feminine Hygiene and Health" and a booklet entitled "Ardine * * * A Boon To Happy Womanhood."

CHARGE: The complaint alleged that the defendant was engaged in the business of distributing and selling *Ardine tablets*, consisting of chloramine T, starch, and sodium bicarbonate; *Smylax tablets*, consisting of an extract of sarsaparilla root and powdered licorice; and *Smylax tonic*, consisting of sarsaparilla extract and flavoring in a simple sirup; and, further, that the defendant had been causing the introduction and delivery for introduction into interstate commerce of such articles which were misbranded as follows:

Smylax tablets and *Smylax tonic*. 502(a)—the labeling of the articles contained false and misleading representations that the articles were adequate and effective treatments for retarding old age; overcoming the lack of hormones in the body; enabling one to keep alive and healthy for a longer life; feeding the glands; overcoming emotional, physical, sexual, and mental difficulties; overcoming a condition of tired muscles, starving nerves, impaired blood circulation, and low resistance to infection; providing vitality; overcoming skin eruptions, general debility, muscle cramps, infections, poisons, head pains, sinus infection, a condition of poisoned blood stream, skin disease, chronic rheumatism, and scrofula; providing a gland food to enable the glands to produce testosterone, progesterone, and cortisone; overcoming angina pectoris, ringworm, psoriasis, and other skin ailments, arthritis, rheumatic fever, prostate gland weakness, menstrual difficulties, menopausal difficulties, nervous headaches, hot flashes, menstrual cramps, emotional upsets, depression, and allergic difficulties; preventing softening of the bones, diabetes, high blood pressure, and heart attacks; and providing good health.

Ardine tablets. 502(a)—the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for providing good health and happiness; enabling one to retain youth, beauty, and vigor; providing a complete germicidal power that will kill all germs and bacteria and remain effective for such purposes for several hours when placed in the vagina; preventing infection, including gonorrhea; and overcoming pyorrhea, ringworm, eczema, and leucorrhea.

DISPOSITION: On 6–28–57, after a hearing at which the defendant appeared, the court entered a preliminary injunction. On 8–8–57, the defendant having failed to answer or otherwise plead to the complaint, a default decree of permanent injunction was entered against the defendant enjoining him against commission of the acts complained of.

5496. Diaplex. (F.D.C. No. 40349. S. No. 72–982 M.)

QUANTITY: 20 12-oz. ctns. at Salt Lake City, Utah.

SHIPPED: 1–18–57, from Canyon City, Colo., by H. W. Pierce.

LABEL IN PART: (Ctn.) "DIAPLEX * * * contains as follows: Calcium Fluoride Calcium Sulfate Calcium Phosphate Iron Phosphate Potassium Chloride Silica Sodium Chloride Iodine Sulphur Pure Phosphate Pure Calcium Boron Protein All these organic minerals were found in this herb. Diaplex: Vitamin Content A, B, B_1, C, D, and traces of others including many valuable minerals naturally compounded * * * Mile Hi Food Co., Denver 11, Colorado."

ACCOMPANYING LABELING: Leaflet entitled "DIAPLEX Distributed by H. W. Pierce * * * NOTICE—Instructions to the Diabetics' Doctor and Patient:"

LIBELED: 7–8–57, Dist. Utah.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for diabetes.

DISPOSITION: 8–30–57. Default—destruction.

5497. Menstruation Tea. (F.D.C. No. 40574. S. No. 72–403 M.)

QUANTITY: 29 ctns. at Detroit, Mich., in possession of Old Chief Medicine Co.

SHIPPED: On an unknown date, from Hammond, Ind.

LABEL IN PART: "Formula No. 226 Menstruation Tea Old Chief Beverage Herb (Mildly Stimulating) Ingredients: Calamus, Lily Root, Ginger Root, Prairie Plant (Yarrow), Black Cohosh, German Rue, Bearberry Leaves, Squaw Weed."

RESULTS OF INVESTIGATION: The article was repackaged and relabeled by the consignee after its shipment as described above.

LIBELED: 8–30–57, E. Dist. Mich.

CHARGE: 502(a)—the representation of the article as "Menstruation Tea," while held for sale, represented and suggested that the article was effective for overcoming menstrual difficulties, which representation was false and misleading since the article was not effective for such purpose.

DISPOSITION: 11–7–57. Default—destruction.

5498. Vi-Jon antiseptic. (F.D.C. No. 40854. S. No. 65–603 M.)

QUANTITY: 43 btls. at Piqua, Ohio, in possession of G. C. Murphy Co.

SHIPPED: 8–21–57, from McKeesport, Pa.

LABEL IN PART: "Vi-Jon * * * Antiseptic * * * Active Ingredients 25% Alcohol, Eucalyptol, Thymol, Menthol, Methyl Salicylate, Benzoic Acid, Boric Acid."

ACCOMPANYING LABELING: Display placard bearing the wording "Murphy's Prevent 'Asiatic Flu' Vi-Jon Mouth Wash 39¢."

RESULTS OF INVESTIGATION: The above-mentioned placard was prepared locally by the consignee for use in promoting the sale of the article.

LIBELED: 10–22–57, S. Dist. Ohio.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was effective for the prevention of Asiatic influenza.

DISPOSITION: 12–13–57. Consent—the placard was destroyed, and the article was delivered to a county institution, for use by the inmates.

5499. Bath minerals. (F.D.C. No. 40844. S. No. 71–565 M.)

QUANTITY: 24 2-lb. jars at Minneapolis, Minn.

SHIPPED: 5–9–57, from Chicago, Ill., by Arkansas Mining Co.

LABEL IN PART: "CONTENTS Mineral contents and parts per million in bath water after directions are followed (1 tablespoonful to ten gallons): Silica 61.20 Iron 0.08 Manganese 0.38 Calcium 62.40 Magnesium 7.60 Sodium 22.80 Potassium 2.12 Carbonate (plus Bicarbonate) 154.00 Chloride 1.90 Sulphate 30.40."

ACCOMPANYING LABELING: Booklet designated "Arkansas Mining Company Confidential Sales Information," leaflets designated "Comfort For Pains Like Those of Arthritis Rheumatism Now Mineral Baths in Your Own Home," booklets designated "Mineral Baths Arkansas Mining Company General Offices: Hot Springs, Ark.," and a display card designated "Enjoy Mineral Baths at Home from Hot Springs, Arkansas."

LIBELED: 10–23–57, Dist. Minn.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was effective in the treatment of arthritis, rheumatism, nervousness, skin and complexion disorders, chronic pains, and a rundown condition.

DISPOSITION: 12–4–57. Default—destruction.

DRUG ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH PACKAGING REQUIREMENTS OF AN OFFICIAL COMPENDIUM

5500. Water for injection. (F.D.C. No. 40324. S. No. 58–099 M.)

QUANTITY: 142 vials at Kansas City, Kans.

SHIPPED: 3–18–57, from Philadelphia, Pa., by Addison Laboratories.

LABEL IN PART: (Vial) "100 cc. Multiple Dose Vial Water For Injection A Ten Dose Container Pyrogen Free Contains: Phenol 0.5% Sterile * * * Physicians & Surgeons Supply, Wichita, Kansas."

RESULTS OF INVESTIGATION: *Water for injection* is a drug recognized by the United States Pharmacopeia. The U.S.P. monograph states under the heading "Packaging and storage,"—"Preserve Water for Injection in single-dose containers holding not more than 1,000 ml. or in multiple-dose containers holding not more than 30 ml. * * * Water for Injection containing no antibacterial agent may be packaged in a multiple-dose container of not greater than 100 ml. size, provided the package is marketed in combination with a medicinal preparation for parenteral administration for which it is to be the solvent."

Examination showed that each vial of the article was closed by a rubber stopper which could be readily penetrated by the ordinary hypodermic needle, thus the contents of the vial could be withdrawn without removal or destruction of the closure.

LIBELED: 6–14–57, Dist. Kans.

CHARGE: 502(g)—the article was a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when shipped, the article was not packaged as prescribed therein, since it was in a multiple dose container holding more than 30 ml. and it did not qualify for an exemption from that packaging provision.

DISPOSITION: 7–24–57. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 5481 TO 5500

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5487, 5494, 5495) Injunction issued.

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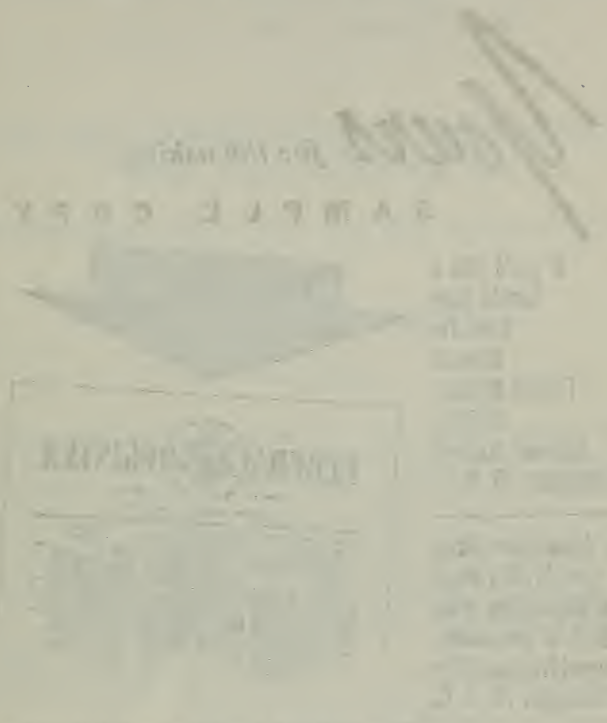

U.S. GOVERNMENT PRINTING OFFICE: 1959

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5501–5520

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *June 26, 1959.*

CONTENTS

VIOLATIVE SALES OF PRESCRIPTION DRUGS

5501. (F.D.C. No. 40449. S. Nos. 69–528/9 M, 69–531/2 M, 69–534/6 M, 69–538/9 M.)

INFORMATION FILED: 11–21–57, E. Dist. Pa., against **David Klebanoff, t/a Galen Drug Store, Philadelphia, Pa., and Ralph Shayne and Marvin L. Doroshow (pharmacists).**

CHARGE: Between 3–30–57 and 4–25–57, *Tuinal capsules* (counts 1, 4, 5, 6, 7, and 8) were dispensed 6 times and *Seconal Sodium capsules* (counts 2, 3, and 9) were dispensed 3 times, upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere by Klebanoff to all counts of information, by Shayne to counts 4, 7, and 9, and by Doroshow to count 8.

DISPOSITION: 2–7–58. The court fined Klebanoff $900, Shayne $150, and Doroshow $50.

5502. Supplement to notice of judgment on drugs and devices, No. 4974. Violation of probation. (F.D.C. No. 38535. S. Nos. 69–532 M, 69–536 M, 69–539 M.)

On 1–27–56, upon a plea of nolo contendere to the charge of dispensing *Tuinal capsules* and *thyroid tablets* without a prescription and *Tuinal capsules* and *Gantrisin tablets* upon request for prescription refills without authorization by the prescriber, the defendant, **Ralph Shayne,** was fined $900 and placed on probation for 3 years.

On 2–18–58, the defendant was brought before the court on a charge of violating his probation with respect to his acts of illegally dispensing *Tuinal capsules* and *Seconal Sodium capsules,* for which acts he was convicted on 2–7–58, as reported above in notice of judgment No. 5501. At the conclusion of the hearing, the court fined the defendant $350 for violation of probation and extended the period of probation for 2 years.

5503. Supplement to notice of judgment on drugs and devices, No. 5140. Violation of probation. (F.D.C. No. 38153. S. No. 35–514 P.)

On 6–29–56, upon a plea of guilty to the charge of dispensing *capsules containing ergot and apiol* twice without a prescription, the defendant, **Isadore Arthur Shenk, t/a Garden Pharmacy, Philadelphia, Pa.,** was fined $2,000, given a sentence of 2 years in prison, which was suspended, and placed on probation for 5 years.

On 5–27–58, the defendant was brought before the court for hearing on a charge of violating his probation by dispensing *Achromycin capsules* once without a prescription. The hearing was concluded on 5–28–58, at which time the court entered an order revoking probation. Under this order, the court directed that the defendant be committed to prison for 6 months and that probation recommence after the termination of the sentence.

An appeal was taken by the defendant to the United States Court of Appeals; and, on 10–28–58, with the consent of the defendant, the appeal was dismissed with prejudice.

5504. (F.D.C. No. 39840. S. Nos. 35–505/6 M.)

INFORMATION FILED: 6–12–57, S. Dist. Ohio, against **James J. Mazzei, t/a Mazzei Pharmacy, Cincinnati, Ohio.**

CHARGE: Between 12–6–56 and 1–2–57, *Aminopterin Sodium tablets* and *Ergoapiol with savin capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 8–9–57. Defendant fined $500 and sentenced to 1 year in jail. Jail sentence suspended.

5505. (F.D.C. No. 40457. S. Nos. 38–284 M, 38–500 M, 38–755 M, 38–760 M, 44–232 M.)

INFORMATION FILED: 1–31–58, W. Dist. Mo., against **A. Brandenberger Drug Co., a corporation, Jefferson City, Mo., and Erben J. Scheidt and Harley E. Nichols (pharmacists).**

CHARGE: Between 10–15–56 and 2–7–57, *penicillin G potassium tablets*, which had been fabricated in the State of Missouri from penicillin G potassium that had been shipped in interstate commerce (counts 1, 2, 3, 4), were dispensed 4 times and *Meticorten tablets* (count 5), which had been shipped in interstate commerce into the State of Missouri (count 5), were dispensed once without a prescription.

PLEA: Guilty by corporation to all 5 counts of information, by Scheidt to counts 2 and 4, and by Nichols to counts 3 and 5.

DISPOSITION: 1–31–58. Corporation fined $250, plus costs, and each individual fined $50.

5506. (F.D.C. No. 39352. S. Nos. 39–962/4 M, 39–966 M, 39–968 M, 39–976/7 M, 39–979/80 M.)

INFORMATION FILED: 11–13–56, N. Dist. Ill., against **Dressler Drugs (a partnership), Chicago, Ill., and John J. Cvopa, Jerome J. Glass, and Ernest Sallemi (pharmacists).**

CHARGE: Between 1–10–56 and 2–23–56, *penicillin G potassium tablets* (counts 4 and 7) and *Gantrisin tablets* (counts 5 and 8) were each dispensed twice and *Duracillin troches* (count 1), *penicillin G potassium troches* (count 2), *Duracillin buffered tablets* (count 3), *Dexedrine Spansule capsules* (count 6), and *amphetamine sulfate tablets* (count 9) were each dispensed once, without a prescription.

PLEA: Nolo contendere by partnership to counts 1 through 7 of information, by Cvopa to counts 1, 2, and 7, by Glass to counts 3, 4, 6, and 9, and by Sallemi to counts 5 and 8.

DISPOSITION: On 12–21–56, the court imposed fines of $1,000 against Glass, $450 against Cvopa, and $300 against Sallemi, plus costs; and, on 11–4–57, the court fined the partnership $200, plus costs.

5507. (F.D.C. No. 40464. S. Nos. 1–455/8 M, 39–750 M, 39–752 M.)

INFORMATION FILED: 2–19–58, N. Dist. Ga., against **James H. Alexander, t/a Wieuca Pharmacy, Atlanta, Ga.**

CHARGE: Between 5–23–57 and 5–31–57, *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed once and *secobarbital sodium capsules* were dispensed twice upon requests for prescription refills without authorization by the prescriber, and *Pentids tablets*, *Gantrisin tablets*, and *Metandren Linguets* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 3–17–58. $300 fine and probation for 2 years.

5508. (F.D.C. No. 40458. S. Nos. 63–486/92 M.)

INFORMATION FILED: 1–6–58, Dist. Utah, against **James L. Kennedy, t/a Kennedy's Drug Store, Logan, Utah, and Grant L. Ballam (pharmacist).**

CHARGE: Between 1–7–57 and 1–28–57, *Dexedrine Sulfate tablets* (counts 1, 2, and 7) were dispensed 3 times and *Equanil tablets* (counts 3 and 5) and *Gantrisin tablets* (counts 4 and 6) were each dispensed twice, upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by Kennedy to all 7 counts of information and by Ballam to counts 2, 5, 6, and 7.

DISPOSITION: 2–20–58. Kennedy fined $2,300 and Ballam $600.

5509. (F.D.C. No. 40450. S. Nos. 64–870/1 M, 64–873 M, 64–941 M.)

INFORMATION FILED: 12–26–57, S. Dist. Ind., against **Stephen W. Tilson (pharmacist and manager for Hook Drugs, Inc.), Indianapolis, Ind.**

CHARGE: Between 1–22–57 and 4–19–57, *pentobarbital sodium capsules* were dispensed twice and *Dexedrine Sulfate tablets* and *phenylbutazone tablets* were each dispensed once, upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 2–20–58. $1,000 fine, plus costs.

5510. (F.D.C. No. 40482. S. Nos. 71–776 M, 71–780 M.)

INFORMATION FILED: 1–15–58, Dist. Minn., against **Hubert J. Renchin, t/a Renchin Drug, St. Paul, Minn., and John A. Hoyer (pharmacist).**

CHARGE: Between 5–9–57 and 5–17–57, *Dexedrine Spansule capsules* and *pentobarbital sodium capsules* were each dispensed once upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 3–24–58. Renchin fined $500 and Hoyer $250. Each defendant placed on probation for 1 year.

5511. (F.D.C. No. 40472. S. Nos. 58–545 M, 58–553/4 M.)

INFORMATION FILED: 1–29–58, Dist. Utah, against **Jimmie W. Johnson, t/a Johnson Drug, Ogden, Utah.**

CHARGE: Between 10–9–56 and 10–30–56, *Dexedrine Sulfate tablets, secobarbital sodium capsules,* and *Butazolidin tablets* were each dispensed once upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 3–20–58. $600 fine.

5512. (F.D.C. No. 40598. S. Nos. 73–364 M, 73–366/7 M, 73–369 M.)

INFORMATION FILED: 9–11–57, N. Dist. Tex., against **Joe Montgomery, Vega, Tex.**

CHARGE: Between 1–16–57 and 2–8–57, *cortisone acetate tablets,* 10 mg. and 15 mg. *Dexedrine Sulfate capsules,* and *penicillin G potassium tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–4–58. $300 fine and probation for 2 years.

5513. (F.D.C. No. 39969. S. Nos. 40–541/2 M, 40–544/5 M, 40–550/1 M.)

INFORMATION FILED: 7–1–57, Dist. Minn., against **Eureka Drug Co. (a partnership), Minneapolis, Minn., and Edward A. Pelant and Marcus W. Connolly (partners).**

CHARGE: Between 3–27–56 and 4–5–56, *Seconal Sodium capsules* (counts 1, 3, and 5) and *Dexedrine Sulfate tablets* (counts 2, 4, and 6) were each dispensed 3 times without a prescription.

PLEA: Guilty by partnership to all 6 counts of information, by Pelant to counts 1 and 2, and by Connolly to counts 3, 4, 5, and 6.

DISPOSITION: 8–23–57. Partnership fined $500 and Pelant and Connolly $1,000 and $400, respectively.

5514. (F.D.C. No. 39829. S. Nos. 20–570 M, 61–767 M.)

INFORMATION FILED: 11–15–56, Dist. Columbia, against **Vernon L. Adams, alias "Dimples," Washington, D.C.**

CHARGE: Between 9–18–56 and 9–29–56, *dextro-amphetamine sulfate tablets, amphetamine sulfate tablets,* and *secobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 12–13–56, and was concluded on 12–17–56, with the return of a verdict of guilty by the jury. On 1–4–57, the defendant was given a sentence of 180 days in jail. The case was appealed to the Municipal Court of Appeals for the District of Columbia; and, on 9–16–57, the following opinion was handed down by that court:

QUINN, *Associate Judge:* "Appellant was charged by the District of Columbia in separate informations with dispensing certain drugs on two different occasions although he was not a licensed pharmacist, in violation of Code 1951, 2–601. He was also prosecuted by the United States on a two-count information for the same acts as a violation of 21 U.S.C. §§ 331(k), 352(d), and 353(b)(1)(B). The cases were consolidated for trial, a jury found him guilty of all charges, and these appeals followed. The only errors assigned relate to the reception of certain evidence and the sufficiency of the government's evidence to establish continuous custody of the drugs up to the time of trial. It is conceded that the same evidence was necessary to prove all the charges and thus our decision on these allegations of error will be dispositive of all appeals.

"The testimony of a police officer on behalf of the government indicated that appellant had delivered the drugs to him while he was working as an undercover agent. During his cross-examination by defense counsel, the following colloquy occurred:

" 'Q. I will ask you this, sir: did you search this man's record to find out if he had a record for narcotics: Adams?

" 'A. At what time?

" 'Q. Any time during your investigation or tour of duty in this case.

" 'Yes, sir.

" 'Did you ever find that he had any narcotic record: Adams?

" 'A. Not on narcotics, sir.'

The prosecutor contended that these questions in effect placed appellant's character in issue and that he was therefore entitled to introduce into evidence the records of appellant's convictions for certain other offenses. Over objection the trial court upheld this position. Another police officer then testified on direct examination that he had searched appellant's record and ascertained that he had been convicted of the unauthorized use of an automobile, of carrying a deadly weapon, and of robbery. The defense claimed that the alleged conviction for robbery was actually one for assault. This

contention was later shown to be accurate, and the trial judge at the close of the government's case gave a corrective instruction to the jury. Subsequently appellant took the stand and acknowledged the convictions, and the trial judge instructed the jury that they were admitted only for the purpose of impeaching his credibility.

"Appellant complains that it was improper for the prosecutor to adduce testimony of his prior convictions as evidence of bad character since they were unrelated to the specific character trait involved, namely, illegal dealing in narcotics or drugs. Our consideration of this contention requires a brief review of the settled rules of law applicable to character evidence. Character is never an issue in a criminal case unless the defendant chooses to make it one. Only after the defendant has introduced evidence of his good character may the government in rebuttal offer evidence of bad character.[1] Such evidence is confined to that of general reputation. Consequently, specific incidents in the life of the accused may not be shown, but only his reputation in the community. In other words, a witness may state either on direct or on cross-examination only what he has heard, not what he knows, about the defendant.[2] To be admissible the testimony must relate to the specific trait of character involved in the offense charged,[3] unless the defendant seeks to establish a general reputation for honesty and truthfulness.[4] Finally, while character ordinarily is made an issue through the testimony of witnesses for the defendant, it is possible to raise the issue through cross-examination of the government's witnesses and the prosecutor has the right to refute the evidence thus presented.[5]

"Tested by these principles, we do not believe that the question put to the police officer on cross-examination by defense counsel was the proper way to elicit character evidence because it requested knowledge of specific incidents rather than reputation. Since the question could not be justified on any other basis, it should have been stricken as irrelevant. Once admitted, however, the effect of the testimony was to place character in issue, since it tended to establish a good character in appellant, and consequently the government had the right to rebut it. Appellant apparently is conceding that his character was in issue, but argues that it was an issue only to the extent of the character trait involved. We agree. Defense counsel's question was concerned only with narcotics violations and while the drugs involved here were not narcotics,[6] we believe the offenses are similar enough so as to warrant a limitation on the evidence which the government could introduce in rebuttal. Clearly, then, it was error to permit the prosecution to show convictions for unauthorized use of an automobile, carrying a deadly weapon, and assault.

"We are not persuaded, however, that the admission of appellant's prior convictions during the government's case constituted reversible error, for appellant subsequently took the stand and his record was again revealed and was admissible for the purpose of affecting his credibility. Appellant says that the initial error deprived him of any choice and forced him to testify. Under some circumstances[7] this argument might have validity, but here his counsel indicated early in the trial before the admission of his record that he intended to testify. The United States Court of Appeals for the District of Columbia has ruled in comparable situations that the defendant's rights were not prejudiced,[8] and a careful study of the stenographic transcript convinces us that that was the case here.

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[1] *Josey* v. *United States*, 77 U.S. App. D.C. 321, 135 F. 2d 809 (1943).

[2] *Stewart* v. *United States*, 70 App. D.C. 101, 104 F. 2d 234 (1939).

[3] *Morris* v. *District of Columbia*, 75 U.S. App. D.C. 82, 124 F. 2d 284 (1941).

[4] *Michelson* v. *United States*, 335 U.S. 469, 69 S. Ct. 213, 93 L. Ed. 168 (1948).

[5] See, *e.g.*, *Logan* v. *State*, 95 Okl. Cr. 76, 239 P. 2d 1044 (1952); *Brethern* v. *State*, 191 Miss. 151, 2 Co. 2d 798 (1941); 1 Underhill's Criminal Evidence § 192 (5th ed. 1956).

[6] They were amphetamine sulfate and secobarbital sodium.

[7] *Cf. United States* v. *Modern Reed & Rattan Co.*, 159 F. 2d 656 (2nd Cir.), cert. den., 331 U.S. 831, 67 S. Ct. 1510, 91 L. Ed. 1845 (1947).

[8] *Lucas* v. *United States*, 70 App. D.C. 92, 104 F. 2d 225 (1939); *Skiskowski* v. *United States*, 81 U.S. App. D.C. 274, 158 F. 2d 177 (1946).

"Appellant also assigns as error the action of the trial judge in not immediately correcting the mistaken testimony about his conviction for robbery. Since the crime was only one of several and the jury was eventually told the true nature of the offense, we do not think this constituted substantial prejudice, nor can we agree that the lapse of time was of any significance.

"Finally, appellant contends that the government's evidence was insufficient to establish continuous custody of some of the drugs involved. There was testimony that an inspector for the Food and Drug Administration received the evidence in Washington from the police officer, sealed it, and gave it to another inspector to deliver to a storekeeper for the Food and Drug Administration located in Baltimore. At trial, the first inspector and the storekeeper testified, but not the inspector who transmitted the drugs. We do not regard this omission as serious. As the Ninth Circuit stated in an identical situation:

> Carried to its logical conclusion, this "chain of possession" theory would require the Government to prove affirmatively that *each* one of the many mail clerks, Administration clerks and experts, doctors, nurses, express company employees, "and others," handled and cared for the goods so that changes could not occur while the drugs were in their custody. It must also be shown that the products "were not tampered with," say the appellants.
>
> Such a rigorous exaction regarding proof is supported neither by reason nor by authority. If the Government were obliged to establish the absence of "tampering" by every one who had any contact whatsoever with the drugs, the Act would be incapable of enforcement.[9]

We conclude that the inspector's connection with the drugs was only as a courier and that his testimony was not essential."

5515. (F.D.C. No. 40604. S. Nos. 34–297 M, 44–017 M, 44–169 M, 58–055 M, 58–155 M, 58–176 M, 58–221 M, 77–876 M, 77–881 M, 78–139 M.)

INFORMATION FILED: 11–5–57, E. Dist. Okla., against **Frederick B. Oliver, t/a Oliver Clinic, Sallisaw, Okla.**

CHARGE: Between 3–26–57 and 5–9–57, *methamphetamine hydrochloride tablets* were dispensed 10 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–25–57. $1,000 fine.

5516. (F.D.C. No. 40434. S. Nos. 38–784 M, 38–793 M, 38–799 M, 43–315 M, 43–320 M.)

INFORMATION FILED: 10–14–57, W. Dist. Tenn., against **W. Chalmers Sowell (partner in the partnership of Standard Drug Co.), Memphis, Tenn., and Leon Bullock (pharmacist).**

CHARGE: Between 11–15–56 and 1–7–57, *secobarbital sodium capsules* were dispensed 5 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere by Sowell to dispensing the capsules 3 times and by Bullock to dispensing the capsules twice.

DISPOSITION: 10–24–57. $750 fine against each defendant.

5517. (F.D.C. No. 40459. S. Nos. 22–167 M, 68–866 M, 68–871 M.)

INFORMATION FILED: 11–21–57, Dist. N.J., against **Michael Netti, t/a Forest Hills Pharmacy, Newark, N.J.**

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[9] *Pasadena Research Laboratories* v. *United States*, 169 F. 2d 375, 381 (9th Cir.), cert. den., 335 U.S. 853, 69 S. Ct. 83, 93 L. Ed. 401 (1948).

CHARGE: Between 1–5–57 and 7–5–57, a quantity of *chloral hydrate, capsules containing pentobarbital sodium,* and *capsules containing a mixture of Seconal Sodium and Amytal Sodium* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–7–58. $1,000 fine, suspended sentence of 1 year in jail, and probation for 4 years.

5518. (F.D.C. No. 40609. S. Nos. 81–861/3 M.)

INFORMATION FILED: 6–24–57, N. Dist. Tex., against **Herbert Iven Sims, Dallas, Tex.**

CHARGE: Between 12–6–56 and 3–5–57, the defendant caused *Daprisal tablets* to be dispensed to himself without a prescription once at each of 3 different drugstores in Dallas, Tex., by displaying a false, forged, and counterfeit writing purporting to be a prescription for the tablets.

PLEA: Guilty.

DISPOSITION: 6–24–57. Defendant sentenced to 13 months in jail.

5519. (F.D.C. No. 40443. S. Nos. 62–468 M, 62–472 M.)

INFORMATION FILED: 12–12–57, E. Dist. N.Y., against **Sydney S. Luchen, t/a Luchen's Pharmacy, Brooklyn, N.Y.**

CHARGE: On 3–1–57, *Meticorten tablets* were dispensed once without a prescription and *Gantrisin tablets* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 1–9–58. $750 fine.

5520. (F.D.C. No. 38576. S. Nos. 5–041/2 M, 5–044 M, 5–058/9 M, 5–399 M, 17–894 M.)

INDICTMENT RETURNED: 5–29–56, N. Dist. Ill., against **Cosmopolitan Drug Co. (a partnership), Chicago, Ill., and Abraham Weinstein and Melvin Weinstein (partners) and Harold M. Weinstein (an employee of the partnership).**

CHARGE: Between 1–7–55 and 3–30–55, *Savatan capsules* (counts 1 and 2) were dispensed twice and *Gantrisin tablets* (counts 3 to 7, incl.) were dispensed 5 times, without a prescription.

DISPOSITION: A motion for dismissal of the indictment was filed on behalf of the defendants, based on the ground that the indictment was duplicitous in that it charged both the individual members of a partnership and the partnership itself as an entity. Thereafter, following consideration of the briefs and arguments of counsel, the court, on 6–7–57, dismissed the indictment against the partnership.

On 11–25–57, pleas of guilty were entered by Melvin Weinstein to counts 1, 6, and 7 of the indictment, by Abraham Weinstein to counts 2, 3, and 4, and by Harold M. Weinstein to count 5. On the same day, the court fined Melvin and Abraham Weinstein $750 each and Harold M. Weinstein $250.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5502, 5503) Violation of probation.
[2] (5514) Prosecution contested. Contains opinion of the court.
[3] (5520) Prosecution contested.

[1] (5502, 5503) Violation of probation.
[3] (5520) Prosecution contested.

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U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5521–5560

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C.

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

5521. (F.D.C. No. 40444. S. Nos. 45–201/3 M.)

INFORMATION FILED: 1–8–58, W. Dist. Va., against **Mick Lukach (an employee at the White Plains Truck Station), Barren Springs, Va.**

CHARGE: Between 12–13–56 and 5–8–57, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 5–5–58. Defendant placed on probation for 3 years.

5522. (F.D.C. No. 40479. S. Nos. 55–366/8 M.)

INFORMATION FILED: 1–30–58, E. Dist. Ky., against **Millard C. Owens, t/a M. C. Owens Druggist, Covington, Ky.**

CHARGE: Between 7–2–57 and 7–9–57, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4–21–58. $1,500 fine and sentence of 90 days in jail.

5523. (F.D.C. No. 40612. S. Nos. 65–537/8 M.)

INFORMATION FILED: 5–2–58, S. Dist. Ohio, against **Ferdinand J. Weisbrodt, t/a Weisbrodt Hy-Pure Pharmacy, Glendale, Ohio.**

CHARGE: On 10–28–57, *amphetamine sulfate tablets* and *pentobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court without a jury on 5–23–58 and was concluded on 5–26–58, with a return of a verdict of guilty and the imposition of a fine of $1,000.

5524. (F.D.C. No. 40430. S. Nos. 67–495/8 M.)

INFORMATION FILED: 8–30–57, E. Dist. Va., against **Reuben Miller, t/a Rust Manor Pharmacy, Falls Church, Va., and Leo Strauss (pharmacist).**

CHARGE: Between 3–26–57 and 4–13–57, *Dexedrine Sulfate tablets* were dispensed 3 times upon request for prescription refills without authorization by the prescriber and once without a prescription.

PLEA: Guilty by Miller to all 4 counts of information and by Strauss to 2 counts.

DISPOSITION: 6–18–58, Miller fined $3,000 and placed on probation for 2 years; 6–20–58, Strauss fined $1,000 and placed on probation for 2 years.

5525. (F.D.C. No. 40618. S. Nos. 8–486 P, 8–492 P.)

INFORMATION FILED: 8–25–58, N. Dist. N.Y., against **Albert L. Spediacci, t/a Spediacci's Mohawk Pharmacy, Amsterdam, N.Y.**

CHARGE: Between 1–17–58 and 2–3–58, *Dexedrine Sulfate tablets* were dispensed once without a prescription, and *Ansolysen Tartrate tablets* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 9–8–58. $1,000 fine.

5526. (F.D.C. No. 41149. S. Nos. 39–575 M, 53–690 M, 77–569 M.)

INFORMATION FILED: 1–29–58, S. Dist. Ala., against **Frank Schlichting, t/a State Line Truck Stop & Restaurant, Seminole, Ala.**

CHARGE: Between 6–7–57 and 7–16–57, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 3–17–58. $200 fine and probation for 2 years.

5527. (F.D.C. No. 41141. S. Nos. 39–576 M, 76–932 M.)

INFORMATION FILED: 4–1–58, N. Dist. Ga., against **William L. Easterwood and David C. Crocker (employees of Poole's 78 Service Station), Waco, Ga.**

CHARGE: Between 6–18–57 and 8–7–57, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 5–5–58. Each defendant placed on probation for 2 years.

5528. (F.D.C. No. 41142. S. No. 45–204 M.)

INFORMATION FILED: 1–8–58, W. Dist. Va., against **Harry Horsley, t/a Whiteway Truck Stop, Martinsville, Va.**

CHARGE: On 5–24–57, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–10–58. $1,000 fine and probation for 1 year.

5529. (F.D.C. No. 40465. S. Nos. 41–215 M, 71–765 M.)

INFORMATION FILED: 12–19–57, Dist. Minn., against **George F. Setzer and Robert J. Setzer (partners in the partnership of Setzer Pharmacy), St. Paul, Minn.**

CHARGE: Between 3–27–57 and 4–9–57, *secobarbital sodium capsules* were dispensed once by George F. Setzer and *Dexedrine Spansule capsules* were dispensed once by Robert J. Setzer upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 4–28–58. Each defendant fined $25.

5530. (F.D.C. No. 41185. S. Nos. 27–478/9 M, 53–590 M.)

INFORMATION FILED: 5–22–58, E. Dist. La., against **Edgar F. Mayeux, t/a Mayeux's Drug Center, Kenner, La.**

CHARGE: Between 5–16–57 and 5–21–57, *secobarbital sodium capsules* were dispensed twice and *Dexedrine Sulfate tablets* were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 12–10–58. The court fined the defendant $250, imposed a jail sentence for 6 months, which was suspended, and placed the defendant on probation for 5 years.

5531. (F.D.C. No. 41198. S. Nos. 90–063/4 M, 90–106 M, 90–112 M.)

INFORMATION FILED: 5–9–58, E. Dist. Mo., against **Thurman C. Jones (an employee of Dial Pharmacy), Kennett, Mo.**

CHARGE: Between 9–25–57 and 9–27–57 *secobarbital sodium capsules* were dispensed twice and *dextro-amphetamine sulfate tablets* and *meprobamate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7–30–58. $400 fine.

5532. (F.D.C. No. 41157. S. Nos. 75–909/10 M, 75–912/3 M, 76–141 M, 76–163 M.)

INFORMATION FILED: 2–4–58, Dist. Vt., against **Dennis E. Stevens, t/a Edmunds Pharmacy, Lyndonville, Vt.**

CHARGE: 7–22–57 and 7–30–57, *secobarbital sodium capsules, Gantrisin tablets,* and *Benzedrine Sulfate tablets* were each dispensed once upon request for prescription refills without authorization by the prescriber, and *Equanil tablets, Nembutal Sodium capsules* and *Premarin tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 2–17–58. $150 fine.

5533. (F.D.C. No. 41154. S. Nos. 57–241 M, 57–247 M, 57–249 M, 76–996 M, 77–000 M.)

INFORMATION FILED: 1–30–58, S. Dist. Fla., against **Joyce Love Stevens, t/a Stevens Rexall Drugs, Boynton Beach, Fla., and James Michael Bryant and Howard J. Falcon (pharmacists).**

CHARGE: Between 8–13–57 and 8–29–57, *secobarbital sodium capsules* (counts 1 and 2) were dispensed twice and *pentobarbital sodium capsules* (counts 3, 4, and 5) were dispensed 3 times upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty by Stevens to all counts of information, by Bryant to count 4, and by Falcon to counts 1, 2, 3, and 5.

DISPOSITION: 7–11–58. Stevens fined $500; Falcon, $200; and Bryant, $50.

5534. (F.D.C. No. 41139. S. Nos. 78–501/4 M.)

INFORMATION FILED: 1–29–58, W. Dist. Mo., against **Warner Drugs, Inc., Gladstone, Mo., and Henry H. Ronnau and Charles M. Martin (pharmacists).**

CHARGE: Between 8–12–57 and 8–23–57, *secobarbital sodium capsules* were dispensed 4 times upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty by corporation to all 4 counts of information, by Ronnau to 3 counts, and by Martin to 1 count.

DISPOSITION: 2–28–58. Corporation fined $200, plus costs; Ronnau, $300; and Martin, $100.

5535. (F.D.C. No. 41749. S. Nos. 79–819 M, 24–802/4 P.)

INFORMATION FILED: 7–8–58, W. Dist. Wis., against **Webbens Drugs, Inc., Rhinelander, Wis.**

CHARGE: Between 12–19–57 and 1–28–58, *secobarbital sodium capsules* were dispensed 3 times and *Ergotrate Maleate tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 9–9–58. $400 fine.

5536. (F.D.C. No. 41755. S. Nos. 8–276/7, P, 8–280 P, 8–490 P.)

INFORMATION FILED: 8–25–58, N. Dist. N.Y., against **Ralph D. Robertson and Anthony J. Lolos (pharmacists), Amsterdam, N.Y.**

CHARGE: Between 1–27–58 and 2–11–58, *secobarbital sodium capsules* were dispensed three times and *Gantrisin tablets* were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by Robertson to dispensing *secobarbital sodium capsules* once and *Gantrisin tablets* once and guilty by Lolos to dispensing *secobarbital sodium capsules* twice.

DISPOSITION: 10–23–58. Each defendant fined $750.

5537. (F.D.C. No. 40452. S. Nos. 50–246 M, 50–252 M, 60–991 M, 60–998 M, 61–010 M, 61–012 M.)

INDICTMENT RETURNED: 4–11–58, Dist. Mass., against **Nelson's Pharmacy, Inc., Lynn, Mass., and Hyman Levy (pharmacist).**

CHARGE: Between 2–5–57 and 2–13–57, *pentobarbital sodium capsules*, *Gantrisin tablets*, and *Miltown tablets* were each dispensed twice upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 9–12–58. Fine of $500 against corporation and $250 against individual. Individual also sentenced to 2 years in jail; jail sentence suspended and probation for 3 years.

5538. (F.D.C. No. 40485. S. Nos. 33–382 M, 33–384 M, 33–391 M, 33–398 M.)

INFORMATION FILED: 1–16–58, Dist. Nebr., against **Fred Rathgeber, t/a Fred's Pharmacy, Omaha, Nebr., and Clarence Meany (pharmacist).**

CHARGE: Between 5–29–57 and 7–10–57, *pentobarbital sodium capsules* were dispensed 4 times without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 4–21–58, and was terminated on 4–22–58, with the return of a verdict of not guilty as to both defendants.

5539. (F.D.C. No. 40484. S. Nos. 49–187 M, 49–189 M, 72–790 M.)

INFORMATION FILED: 3–18–58, N. Dist. Ill., against **Goodman Drug & Liquor, Inc., Chicago, Ill., and Morton S. Elboom (secretary, manager, and pharmacist for the corporation).**

CHARGE: Between 4–1–57 and 8–19–57, *dextro-amphetamine sulfate capsules* were dispensed twice and *Metandren Linguets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–7–58. Corporation fined $750, plus costs, and individual fined $300.

5540. (F.D.C. No. 41176. S. Nos. 68–706/7 M, 68–714 M.)

INFORMATION FILED: 6–9–58, E. Dist. N.Y., against **Mintzer Pharmacy, Inc., Brooklyn, N.Y., Leo Goldfarb (vice president), and Fred Srebnick and Irwin Brackman (pharmacists).**

CHARGE: Between 6–11–57 and 7–10–57, *Miltown tablets* were dispensed twice and *dextro-amphetamine sulfate tablets* were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by corporation and Srebnick to dispensing a quantity of *Miltown tablets* once, by Goldfarb to dispensing another quantity of *Miltown tablets* once, and by Brackman to dispensing *dextro-amphetamine sulfate tablets* once.

DISPOSITION: 10–9–58. Corporation fined $200; Goldfarb, $250; and Srebnick and Brackman each $150.

5541. (F.D.C. No. 41144. S. Nos. 57–090 M, 57–093 M.)

INFORMATION FILED: 2–19–58, N. Dist. Ga., against **Clayton B. Wheeler, t/a Wheeler Peachtree Pharmacy, Atlanta, Ga.**

CHARGE: Between 6–4–57 and 6–11–57, *dextro-amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 3–17–58. $500 fine and probation for 2 years.

5542. (F.D.C. No. 39203. S. Nos. 23–279 M, 23–616 M, 23–618 M, 49–723 M, 49–725 M.)

INFORMATION FILED: 10–19–56, Dist. R.I., against **Carmine Mascio and Julia Mascio, t/a Marieville Pharmacy, Inc.**

CHARGE: On 3–26–56, Julia Mascio caused *dextro-amphetamine sulfate tablets* to be dispensed once upon request for a prescription refill without obtaining authorization by the prescriber, and between 4–5–56 and 4–26–56, Carmine Mascio caused *dextro-amphetamine sulfate capsules* and *pentobarbital sodium capsules* to be dispensed twice each without a prescription.

PLEA: Guilty.

DISPOSITION: 6–21–57. Julia Mascio placed on probation for 1 year. Carmine Mascio fined $750 and sentenced to jail for 7 months; jail sentence suspended and probation for 1 year.

On 8–15–57, a petition for revocation of probation was filed against Carmine Mascio, and on 8–26–57, the court revoked the probation and sentenced the defendant to serve the jail sentence.

5543. (F.D.C. No. 41201. S. Nos. 72–235/9 M.)

INFORMATION FILED: 5–20–58, N. Dist. Ill., against **William H. Kuhn Drug Store (a partnership), Joliet, Ill., and William H. Shaw and John Vidano (partners in the partnership) and Nicholas B. Kozar (pharmacist).**

CHARGE: Between 9–5–57 and 10–29–57, *AM Plus capsules* (counts 1 and 2) were dispensed twice and *Neopenzine tablets* (counts 3, 4, and 5) were dispensed 3 times without a prescription.

PLEA: Nolo contendere by partnership to all 5 counts of information, by Vidano to counts 2 and 5, by Shaw to counts 3 and 4, and by Kozar to count 1.

DISPOSITION: 6–9–58. Partnership fined $250, plus costs; Shaw and Vidano, each $600; and Kozar, $100.

5544. (F.D.C. No. 40445. S. Nos. 27–590 M, 53–014/6 M.)

INFORMATION FILED: 11–13–57, S. Dist. Miss., against **Paul Rogers, Hattiesburg, Miss.**

CHARGE: Between 10–23–56 and 11–5–56, *methamphetamine hydrochloride tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 5–19–58. $150 fine and 9-month jail sentence; jail sentence suspended.

5545. (F.D.C. No. 37862. S. Nos. 87–355 L, 87–357 L.)

INFORMATION FILED: 6–8–55, Dist. Mont., against **Lewis Guy Belveal (manager of Woody Drug), Butte, Mont., and Elwood Wilson (a pharmacist).**

CHARGE: On 9–23–54, Lewis Belveal dispensed at one time a number of *pentobarbital sodium capsules* without a prescription; and on 9–24–54, Elwood Wilson dispensed at one time without a prescription a number of *green, yellow, and pink tablets containing, among other ingredients, amphetamine hydrochloride, thyroid, atropine sulfate, and phenobarbital.*

PLEA: Guilty.

DISPOSITION: 9–19–55. Each defendant fined $100 and sentenced to 6 months in jail; jail sentence suspended and probation for 3 years.

On 5–13–57, Lewis Belveal was brought before the court on a charge of violating his probation by dispensing, on 5–1–56 and 5–5–56, a number of *amphetamine sulfate tablets* without a prescription. After hearing the testimony with respect to the violations and the ill health of the defendant, the court admonished the defendant and continued his probation.

5546. (F.D.C. No. 41739. S. Nos. 36–465/7 P.)

INFORMATION FILED: 6–6–58, E. Dist. Mo., against **Larkin Williams, t/a Larkin's Confectionary, St. Louis, Mo.**

CHARGE: Between 2–27–58 and 2–28–58, *pentobarbital sodium capsules* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 6–26–58. $800 fine and probation for 3 years.

5547. (F.D.C. No. 41743. S. Nos. 30–998 M, 31–000 M, 56 P, 58 P.)

INFORMATION FILED: 7–21–58, S. Dist. Ind., against **O. Kenneth Chicon, t/a Ken's Prescription Pharmacy, Washington, Ind.**

CHARGE: Between 11–22–57 and 1–22–58, *pentobarbital sodium capsules* were dispensed twice upon request for prescription refills without authorization by the prescriber and *thyroid tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9–22–58. $800 fine, plus costs.

5548. (F.D.C. No. 41734. S. Nos. 72–222/4 M, 14–745 P.)

INFORMATION FILED: 6–30–58, N. Dist. Ill., against **Julius Ellenby (an apprentice pharmacist), Chicago, Ill.**

CHARGE: Between 8–12–57 and 1–16–58, *penicillin G potassium tablets* and *AM Plus capsules* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9–10–58. $600 fine, plus costs.

5549. (F.D.C. No. 40617. S. No. 81–689 M.)

INFORMATION FILED: 9–23–58, S. Dist. Tex., against **Oran W. Mobley, t/a Mobley's Clark Street Drug, Houston, Tex.**

CHARGE: On 5–1–57, *penicillin G potassium tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9–26–58. $350 fine.

5550. (F.D.C. No. 40616. S. No. 81–694 M.)

INFORMATION FILED: 9–23–58, S. Dist. Tex., against **Acres Home Drug Store (a partnership), Houston, Tex., and Dan L. Lasky (a partner).**

CHARGE: On 5–8–57, *penicillin G potassium tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9–26–58. $200 fine against each defendant.

5551. (F.D.C. No. 41719. S. Nos. 65–313 M, 65–318 M, 65–729 M, 65–733 M.)

INFORMATION FILED: 5–2–58, N. Dist. Ohio, against **George A. Turner, t/a Turner's Pharmacy, Ashtabula, Ohio, and Ernest P. Smith (pharmacist).**

CHARGE: Between 8–29–57 and 10–15–57, *V-Cillin pulvules* (count 1) and *Premarin tablets* (count 3) were each dispensed once and *Dexedrine Spansule capsules* (counts 2 and 4) were dispensed twice without a prescription.

PLEA: Guilty by Turner to all 4 counts of information and by Smith to counts 1 and 4.

DISPOSITION: 5–16–58. Turner—$500 fine and probation for 1 year; Smith—probation for 1 year.

5552. (F.D.C. No. 40469. S. Nos. 51–726 M, 51–729 M.)

INFORMATION FILED: 1–6–58, Dist. Colo., against **James Francis LeMon, t/a Yorfax Drug, Denver, Colo.**

CHARGE: Between 9–22–56 and 10–13–56, *delta–1–hydrocortisone and acetylsalicylic acid tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 5–2–58. $400 fine and probation for 2 years.

5553. (F.D.C. No. 41710. S. Nos. 71–001/4 M, 79–743 M.)

INFORMATION FILED: 5–19–58, W. Dist. Wis., against **Leslie C. McGill, t/a Peoples Drug Co., Janesville, Wis., and Donald L. Taber (pharmacist).**

CHARGE: Between 7–9–57 and 7–23–57, *Equanil tablets* (counts 1, 2, and 4) were dispensed 3 times and *Nembutal Sodium capsules* (counts 3 and 5) were dispensed twice upon request for prescription refills without authorization by the prescriber.

PLEA: Guilty by McGill to all 5 counts of information and by Taber to counts 1, 2, 4, and 5.

DISPOSITION: 6–16–58. Each defendant placed on probation for 1 year.

5554. (F.D.C. No. 40480. S. Nos. 61–150 M, 61–248 M, 61–255 M, 61–296/7 M, 61–403 M.)

INFORMATION FILED: 3–7–58, Dist. Mass., against **John Colluccini, t/a Grant Drug Co., East Boston, Mass.**

CHARGE: Between 4–25–57 and 5–13–57, *Nembutal Sodium capsules* were dispensed twice and *Gantrisin tablets, Valmid tablets,* and *Equanil tablets* were each dispensed once upon request for prescription refills without authorization by the prescribers, and *Premarin tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–1–58. $250 fine and probation for 1 year.

5555. (F.D.C. No. 41725. S. Nos. 65–201 M, 65–728 M, 65–732 M.)

INFORMATION FILED: 5–13–58, N. Dist. Ohio, against **Cook's Drug Store (a partnership), Ashtabula, Ohio, Adolphus S. Hale (a partner in the partnership), and Edward N. Watt (pharmacist).**

CHARGE: Between 8–29–57 and 10–15–57, *Achromycin capsules* (count 1), *Premarin tablets* (count 2), and *Meticorten tablets* (count 3) were each dispensed once without a prescription.

PLEA: Guilty by partnership and Hale to all 3 counts of information and by Watt to counts 1 and 3.

DISPOSITION: 6–13–58. The court fined the partnership $500, suspended the fine, fined Hale $1,000, and placed Hale and Watt on probation for 1 year.

5556. (F.D.C. No. 41722. S. Nos. 65–202 M, 65–308 M, 65–314 M, 65–730/1 M.)

INFORMATION FILED: 5–13–58, N. Dist. Ohio, against **Joki's Pharmacy (a partnership), Ashtabula, Ohio, and Erick Joki and Annabelle M. Joki (partners).**

CHARGE: Between 8–20–57 and 10–15–57, *Dexedrine Spansule capsules* (counts 1 and 2) were dispensed twice and *V-Cillin pulvules* (count 3), *Premarin tablets* (count 4) and *Meticorten tablets* (count 5) were each dispensed once, without a prescription.

PLEA: Guilty by partnership and Erick Joki to all counts of information and by Annabelle M. Joki to counts 1 and 5.

DISPOSITION: 6–27–58. The court fined the partnership $100, suspended the fine, and placed Erick Joki on probation for 1 year and Annabelle M. Joki on probation for 6 months.

5557. (F.D.C. No. 41193. S. Nos. 1–486/9 M, 57–056/7 M.)

INFORMATION FILED: 12–8–58, N. Dist. Ga., against **Robert L. Parsons (a pharmacist), Atlanta, Ga.**

CHARGE: Between 9–3–57 and 9–11–57, *Dexedrine Sulfate tablets* were dispensed 4 times and *Nembutal Sodium capsules* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 1–21–59. $300 fine and probation for 2 years.

5558. (F.D.C. No. 41197. S. Nos. 61–345 M, 61–353/4 M, 76–076 M, 76–079 M, 76–518 M, 76–586/8 M.)

INFORMATION FILED: 6–18–58, Dist. Mass., against **Selden Drug Co., Inc., t/a Highland Prescription Pharmacy, Newton Highlands, Mass., and Joseph Selden (president) and Samuel Bardisian (pharmacist).**

CHARGE: Between 9–13–57 and 10–2–57, *Dexedrine Sulfate tablets* (counts 6 and 9) were dispensed twice without a prescription, and *Banthine tablets* (counts 1, 3, and 5) and *Nembutal Sodium capsules* (counts 2, 4, and 7) were each dispensed three times and *Dexedrine Sulfate capsules* (count 8) were

dispensed once, upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty by corporation to all counts of information, by Selden to counts 2, 5, 6, 7, 8, and 9, and by Bardisian to counts 1, 3, and 4.

DISPOSITION: 1–26–59. Corporation fined $500; Selden fined $300, given a jail sentence of 6 months, which was suspended, and placed on probation for 1 year; and Bardisian fined $200 and placed on probation for 1 year.

5559. (F.D.C. No. 41156. S. Nos. 57–436 M, 57–444 M, 76–943 M, 76–946 M.)

INFORMATION FILED: 4–7–58, N. Dist. Ga., against **James Curtis Kimsey, t/a Kimsey's Drug Store, Toccoa, Ga., and Cyril A. Williams (a pharmacist).**

CHARGE: Between 9–23–57 and 9–27–57, *Dexedrine Sulfate tablets* and *methamphetamine hydrochloride tablets* were each dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 10–13–58. The court fined Kimsey $1,000 and placed Williams on probation for 2 years.

5560. (F.D.C. No. 41721. S. Nos. 68–565 M, 78–757 M.)

INFORMATION FILED: 6–20–58, E. Dist. N.Y., against **Harry Margolis, t/a Margolis Pharmacy, Brooklyn, N.Y.**

CHARGE: On 9–4–57 *Dexedrine Spansule capsules* and on 10–29–57 *Gantrisin tablets* were dispensed upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 11–28–58. $500 fine.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 5521 TO 5560

PRODUCTS

[1] (5523, 5538) Prosecution contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5523, 5538) Prosecution contested.

[1] (5523, 5538) Prosecution contested.

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U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5561–5580

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent and (2) criminal proceedings terminated upon pleas of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *August 13, 1959*

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*For failure to bear adequate directions or warning statements, see No. 5561; omission of, or unsatisfactory, ingredients statements, Nos. 5561, 5562; failure to bear label containing an accurate statement of the quantity of the contents, No. 5561.

514148—59

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5561–5580

Adulteration, Section 501(a)(1), the article consisted in part of a filthy substance; Section 501(a)(2), the article had been prepared under insanitary conditions; Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(2), the article was in package form, and it failed to bear a label containing an accurate statement of the quantity of contents; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 503(b)(1), the article was dispensed without a prescription from a practitioner licensed by law to administer the article; Section 503(b)(4), the article was subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

VIOLATIVE SALES OF PRESCRIPTION DRUGS

5561. Various drugs. (F.D.C. No. 40603. S. Nos. 41–889/91 M, 55–785 M, 55–787/9 M, 55–791 M, 84–801 M.)

INDICTMENT FILED: 1–14–58, E. Dist. Ky., against John Byron Miller, t/a J. B. Miller, pharmacist, Williamstown, Ky.

CHARGE: Between 6–1–57 and 6–12–57, *penicillin tablets* were dispensed three times and *cortisone acetate tablets* were dispensed twice without a prescription, which acts of dispensing were caused to be done by the defendant while the tablets were being held for sale after shipment in interstate commerce and which resulted in the tablets being misbranded under 503(b)(1).

In addition, various articles, namely, a number of *pink tablets* and *mephenesin tablets* and quantities of a *yellow oil* and a *liquid medicine* were caused to be introduced into interstate commerce by the defendant at Williamstown, Ky., for delivery to Albany, N.Y., and Nashville, Tenn., between the latter part of 1956 and 7–15–57. The articles were misbranded as follows:

502(b)(2)—the labels of the articles bore no statement of the quantity of contents.

502(e)(1)—the labels of the articles failed to bear the common or usual names of the articles.

502(e)(2)—the articles, other than the *yellow oil*, were fabricated from two or more ingredients, and the labels failed to bear the common or usual name of each active ingredient.

502(f)(1)—the labeling of the articles failed to bear adequate directions for use since the labeling failed to state the conditions and purposes for which the articles were intended.

503(b)(1)—the *mephenesin tablets* were dispensed without a prescription.

PLEA: Guilty.

DISPOSITION: 4–21–58. Sentence of 90 days in jail and fine of $2,250.

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5562. Del-Caps. (F.D.C. No. 41316. S. Nos. 70–416/8 M.)

QUANTITY: 1 drum containing 24,850 capsules, 1 drum containing 49,850 capsules, and 1 drum containing 20,300 capsules at Philadelphia, Pa.

SHIPPED: 7–3–57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: (24,850-capsule lot) "Lot No. 2881 * * * Formula Del-Caps 10 Mg."; (49,850-capsule lot) "Del-Caps 15 Timed Disintegration Capsule * * * Each Capsule Contains: Dextro Amphetamine Sulfate 15 mg. * * * provides for the disintegration of the contents throughout a period of 6–10 hours" and "Lot No. 2974 * * * Formula: Del-Caps 15 mg."; (20,300-capsule lot) "Lot No. 2974 * * * Formula: Del-Caps 15 mg.," "Del-Caps Time Disintegration Capsules * * * Dextro amphetamine sulfate 10 mg. * * * provides for the disintegration of the contents throughout a period of 6–10 hours," and "Del-Caps 15 Timed Disintegration Capsule * * * Dextro amphetamine sulfate 15 mg. * * * provides for the disintegration of the contents throughout a period of 6–10 hours."

RESULTS OF INVESTIGATION: Examination showed that the capsules in the 24,850-capsule lot contained 15 mg. per capsule of dextro-amphetamine sulfate, of which 80 percent was released within 1 hour rather than uniformly over a 6- to 10-hour period; that the capsules in the 49,850-capsule lot contained 15 mg. per capsule of dextro-amphetamine sulfate, of which 81 percent was released within 2 hours rather than uniformly over a 6- to 10-hour period; and that the 20,300-capsule lot contained 10 mg. per capsule of dextro-amphetamine sulfate, of which 90 to 99 percent was released within 2 hours rather than uniformly over a 6- to 10-hour period.

LIBELED: 1–3–58, E. Dist. Pa.

CHARGE: 501(c)—when shipped, the quality of the article in all lots fell below that which it purported and was represented to possess since the capsules failed to disintegrate as indicated; 502(a)—the statement "Timed Disintegration Capsules * * * provides for the disintegration of the contents throughout a period of 6–10 hours" on the labels of the 49,850- and 20,300-capsule lots was false and misleading; 502(e)(2)—the label of the capsules in the 24,850-lot failed to bear the common or usual name of each active ingredient; and 503(b)(4)—the capsules in the 24,850-capsule lot were a drug subject to 503(b)(1), and the label failed to bear the statement "Caution: Federal law prohibits dispensing without a prescription."

DISPOSITION: 2–26–58. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

5563. Saccharin tablets and vitamin B_{12} tablets. (F.D.C. No. 40602. S. Nos. 47–475 M, 59–895 M.)

INFORMATION FILED: 10–15–57, Dist. N.J., against Lit Sales Co., Inc., Newark, N.J., and Stuart W. Lazarus, president.

SHIPPED: Between 6–4–56 and 6–28–56, from the State of New Jersey into the States of Illinois and New York.

LABEL IN PART: (Btl.) "1000 ¼ Grain Saccharin Tablets Effervescent Lit Drug Company Newark, N.J. Distributor" and "100 Tablets Vitamin B–12 25 mcg."

CHARGE: 501(a)(1)—contained rodent hairs, fibers, bristles, and nondescript dirt; and 501(a)(2)—prepared under insanitary conditions.

PLEA: Guilty.

DISPOSITION: 5–9–58. Each defendant fined $1,000.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5564. Digitoxin tablets. (F.D.C. No. 40546. S. No. 62–191 M.)

QUANTITY: 35 1,000-tablet btls., 178 100-tablet btls., and 1 unlabeled drum containing 102,500 tablets at New York, N.Y.

SHIPPED: Digitoxin powder was shipped on 5–17–56, from Paris, France.

LABEL IN PART: (Btl.) "Bryant * * * Tablets Digitoxin USP 0.2 Mg."

RESULTS OF INVESTIGATION: The digitoxin powder, which was shipped as described above, was used to prepare the *digitoxin tablets*.

Examination showed that the tablets contained not more than 83.1 percent of the declared amount of digitoxin.

LIBELED: 8–23–57, S. Dist. N.Y.

CHARGE: 501(b)—the strength of the article, while held for sale, differed from the standard for digitoxin tablets set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin.

DISPOSITION: 10–9–57. Default—destruction.

5565. Digitoxin tablets. (F.D.C. No. 40196. S. No. 68–398 M.)

QUANTITY: 1 drum of 99,800 tablets at New York, N.Y.

SHIPPED: Digitoxin powder was shipped on 3–8–56 and 11–16–56 from Paris, France.

LABEL IN PART: "Digitoxin Tablets Pink 0.1 mg."

RESULTS OF INVESTIGATION: The *digitoxin tablets* were prepared from the powder, which had been shipped as described above.

Examination showed that the tablets contained 80.3 percent of the declared amount of digitoxin.

LIBELED: 6–5–57, S. Dist. N.Y.

*See also No. 5562.

CHARGE: 501(b)—the strength of the article, while held for sale, differed from the standard for digitoxin tablets set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin.

DISPOSITION: 10–11–57. Default—destruction.

5566. Digitoxin tablets. (F.D.C. No. 40642. S. No. 68–991 M.)

QUANTITY: 50,000 tablets in a bulk container at Long Island City, N.Y.

SHIPPED: 1–14–57, from Paris, France.

LABEL IN PART: "Digitoxin 0.2 mgm."

RESULTS OF INVESTIGATION: The shipment described above consisted of digitoxin powder, which was subsequently used in preparing the above-described tablets.

Examination showed that the tablets contained not more than 82 percent of the declared amount of digitoxin.

LIBELED: 10–7–57, E. Dist. N.Y.

CHARGE: 501(b)—the strength of the article, while held for sale, differed from the standard for digitoxin tablets set forth in the United States Pharmacopeia since the article contained less than 90 percent of the declared amount of digitoxin.

DISPOSITION: 11–8–57. Default—destruction.

5567. Soluble saccharin. (F.D.C. No. 40696. S. No. 68–971 M.)

QUANTITY: 1 100-lb. drum at New York, N.Y.

SHIPPED: From Holland.

LIBELED: 10–22–57, S. Dist. N.Y.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for soluble saccharin set forth in the United States Pharmacopeia since the article exceeded the heavy metals limit of 20 parts per million prescribed by the standard.

DISPOSITION: 11–22–57. Default—destruction.

5568. Chorionic gonadotropin. (F.D.C. No. 40929. S. No. 57–847 M.)

QUANTITY: 25 boxes, 2 vials each, at Atlanta, Ga.

SHIPPED: 7–25–57, from Los Angeles, Calif.

LABEL IN PART: "Chorionic Gonadotropin 5,000 I.U. For Preparation of Solution in Intramuscular Injection" and "10 cc. Vial Diluent for Chorionic Gonadotropin."

RESULTS OF INVESTIGATION: Analysis showed that the article contained substantially less than 5,000 I.U. of chorionic gonadotropin potency per vial.

LIBELED: 10–31–57, N. Dist. Ga.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported or was represented to possess; and 502(a)—the label statement "Chorionic Gonadotropin 5,000 I.U." was false and misleading.

DISPOSITION: 12–9–57. Default—destruction.

5569. Chorionic gonadotropin. (F.D.C. No. 40923. S. No. 67–814 M.)

QUANTITY: 7 boxes, 2 vials each, at Tulsa, Okla.

SHIPPED: 7–15–57, from Los Angeles, Calif.

LABEL IN PART: "10 cc. Vial Diluent for Chorionic Gonadotropin * * * Contains 0.5% Phenol" and "Chorionic Gonadotropin 5,000 I.U. * * * For Intramuscular Injection Only."

RESULTS OF INVESTIGATION: Analysis showed that the article contained substantially less than 5,000 I.U. of chorionic gonadotropin potency per vial.

LIBELED: 11–7–57, N. Dist. Okla.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess; and 502(a)—the label statement "Chorionic Gonadotropin 5,000 I.U." was false and misleading.

DISPOSITION: 12–2–57. Default—destruction.

5570. Del-Caps. (F.D.C. No. 40851. S. No. 59–057 M.)

QUANTITY: 1 drum containing 21,000 capsules, 4 1,000-capsule btls., 8 500-capsule btls., and 18 100-capsule btls. at Philadelphia, Pa.

SHIPPED: 6–4–57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: (Drum) "Del-Caps" 15 Timed Disintegration Capsule. Each Capsule Contains: Dextro Amphetamine Sulfate 15 mg. * * * provides for the disintegration of the contents throughout a period of 6–10 hours * * * Delmar Pharmacal Corp."

RESULTS OF INVESTIGATION: The capsules in the btls. had been repackaged by the dealer from the above-mentioned bulk drum.

Examination showed that the article contained the labeled amount of dextro-amphetamine sulfate; that 68 percent of the dextro-amphetamine sulfate ingredient was released within the first 2 hours; and that the entire labeled amount of such ingredient was released within 5 hours.

LIBELED: 10–23–57, E. Dist. Pa.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess, namely, the capsules of the article failed to disintegrate at a uniform rate over a 6- to 10-hour period; and 502(a)—the label of the article contained a false and misleading representation that the dextro-amphetamine sulfate ingredient of the article would be released at a uniform rate over a 6- to 10-hour period.

DISPOSITION: 11–25–57. Default—destruction.

5571. Pyrilamine maleate capsules. (F.D.C. No. 40905. S. No. 68–952 M.)

QUANTITY: 20 ctns. at Woodside, N.Y.

SHIPPED: 6–19–57, from Philadelphia, Pa., by Lustgarten Laboratories, Inc.

LABEL IN PART: "1000 Capsules Timcaps Pyrilamine Maleate 75 Mg. Timed Disintegration Capsule Each Capsule Contains 75 Mg. Pyrilamine Maleate Released gradually and equivalent to 3 doses of 25 mg. over a period of approximately 8 hours * * * Control 6668 * * * Distributed by Henry Schein Woodside, L.I., N.Y."

RESULTS OF INVESTIGATION: Examination showed that the article contained the labeled amount of pyrilamine maleate and that it released 86 percent of its pyrilamine maleate content within 2 hours and 94 percent in 6 hours.

LIBELED: 10–29–57, E. Dist. N.Y.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess, namely, the capsules of the article failed to disintegrate at a uniform rate over an 8-hour period; and 502(a)—the label statement "Timed Disintegration Capsule Each Capsule Contains 75 Mg. Pyrilamine Maleate Released gradually and equivalent to 3 doses of 25 mg. over a period of approximately 8 hours" was false and misleading as applied to a product which did not release the drug at a uniform rate over a period of 8 hours.

DISPOSITION: 12–2–57. Default—destruction.

5572. Gardophen. (F.D.C. No. 40927. S. No. 48–728 M.)

QUANTITY: 11 btls. at Chicago, Ill.

SHIPPED: 7–15–57, from Philadelphia, Pa., by Garde Drug Co.

LABEL IN PART: "One Gallon Garde Gardophen (Elixir Hyoscyamine Comp.) * * * Each 5 cc (1 teaspoonful) contains: Phenobarbital (¼ Gr.). . . . 16.20 mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 118 percent of the labeled amount of phenobarbital.

LIBELED: 10–31–57, N. Dist. Ill.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it was represented or purported to possess since it contained more than the labeled amount of phenobarbital; and 502(a)—the label statement "Each 5 cc (1 teaspoonful) contains: Phenobarbital (¼ Gr.). . . . 16.20 mg." was false and misleading.

DISPOSITION: 12–3–57. Default—destruction.

5573. Haltron capsules and Haloplex capsules. (F.D.C. No. 40622. S. Nos. 68–981/2 M.)

QUANTITY: 4 100-capsule btls. and 1 500-capsule btl. of *Haltron capsules* and 10 100-capsule btls. of *Haloplex capsules* at Jersey City, N.J.

SHIPPED: 6–6–57 and 6–18–57, from Brooklyn, N.Y., by Halsey Drug Co.

LABEL IN PART: "C–1010 Blue Cross * * * Haltron Capsules Whole Liver with Ferrous Sulfate" and "C–1011 Blue Cross * * * Capsules Haloplex (liver B–12 Iron and Vitamins)."

RESULTS OF INVESTIGATION: Analyses showed that the *Haltron capsules* contained less than 50 percent of the declared amount of thiamine chloride (vitamin B_1) and that the *Haloplex capsules* contained less than 50 percent of the declared amount of vitamin C (ascorbic acid).

LIBELED: 9–5–57, Dist. N.J.

CHARGE: 501(c)—the strength of the articles, when shipped, differed from that which they purported and were represented to possess, namely, (*Haltron capsules*) 1.0 mg. of thiamine chloride and (*Haloplex capsules*) 50 mg. of ascorbic acid; and 502(a)—the statements on the label of the *Haltron capsules* "Each Capsule Contains * * * Thiamin Chloride 1.0 mg." and on the label of the *Haloplex capsules* "Each Capsule Contains * * * Ascorbic Acid 50 mg." were false and misleading.

DISPOSITION: 10–14–57. Default—destruction.

5574. Colonoid capsules. (F.D.C. No. 40571. S. No. 39–475 M.)

QUANTITY: 73 12-capsule vials at Charlotte, N. C.

SHIPPED: 3–7–57, from Greenville, S.C., by Lamont Laboratories.

LABEL IN PART: "Colonoid Capsules * * * Each Capsule contains: Purified Hesperidin 100 mg. Ascorbic Acid 100 mg. Salicylamide 2½ grains Phenacetin 2 gr. Caffeine ¼ grain Thenylpyramine Hcl 20 mg."

RESULTS OF INVESTIGATION: Examination showed that the article contained no salicylamide.

LIBELED: 8–21–57, W. Dist. N.C.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it was represented to possess, namely, salicylamide 2½ grains; and 502(a)—the label statement "Each Capsule contains * * * Salicylamide 2½ grains" was false and misleading as applied to a product which did not contain salicylamide, and the label statement "For the relief of symptoms of * * * sinusitis" was false and misleading since the article was not capable of relieving sinusitis.

DISPOSITION: 12–4–57. Default—destruction.

5575. Prophylactics (2 seizure actions). (F.D.C. Nos. 40776, 40786, S. Nos. 80–178 M, 80–182 M.)

QUANTITY: 45 ctns., each containing 12 boxes of 12 units each, and 32 ctns., each containing 48 3-unit boxes, at Minneapolis, Minn.

SHIPPED: 2–28–57 and 5–20–57, from New York, N.Y., by Goodwear Rubber Co., Inc.

LABEL IN PART: "Premier Prophylactics" and "Aristocrat * * * For Prevention of Disease."

RESULTS OF INVESTIGATION: Examination showed that the article was defective in that it contained holes.

LIBELED: 10–10–57 and 10–11–57, Dist. Minn.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the statement on the label of the 45-ctn. lot "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: 12–26–57. Consent—claimed by Akwell Corp., Akron, Ohio, and destroyed.

5576. Prophylactics. (F.D.C. No. 40783. S.No. 84–002 M.)

QUANTITY: 14 ctns., each containing 1 gross, at Keo, Ark.

SHIPPED: 7–3–57, from Akron, Ohio, by Killashun Sales Co.

LABEL IN PART: "Big Chief Lubricated Prophylactics."

RESULTS OF INVESTIGATION: Examination showed that 3.5 percent of the article was defective in that it contained holes.

LIBELED: 10–10–57, E. Dist. Ark.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: 12–16–57. Consent—claimed by Akwell Corp., Akron, Ohio, and destroyed.

5577. Prophylactics. (F.D.C. No. 40754. S. No. 67–952 M.)

QUANTITY: 40 gross at Kansas City, Mo.

SHIPPED: 9–6–57, from Chicago, Ill., by Frank G. Karg.

LABEL IN PART: "Peacocks Redi-Wet Slip-On Skin."

RESULTS OF INVESTIGATION: Examination showed that 14 percent of the article was defective in that it contained holes.

LIBELED: On or about 9–27–57, W. Dist. Mo.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess.

DISPOSITION: 11–18–57. Default—destruction.

5578. Prophylactics. (F.D.C. No. 40750. S. No. 78–011 M.)

QUANTITY: 20 ctns., 3 doz. units each, at Omaha, Nebr.

SHIPPED: 8–27–57, from North Kansas City, Mo., by Dean Rubber Mfg. Co.

LABEL IN PART: "Peacocks Redi-Wet Slip-On Skins."

RESULTS OF INVESTIGATION: Examination showed that 15 percent of the article was defective in that it contained holes.

LIBELED: 9–24–57, Dist. Nebr.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess.

DISPOSITION: 10–25–57. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

5579. Various drugs. (F.D.C. No. 40331. S. Nos. 62–441/45 M.)

QUANTITY: 2 drums containing 23,800 tablets of *Private Formula No. 204291 tablets*, 9 1,000-tablet btls. of *sodium bicarbonate tablets*, 30 50-tablet boxes of *Laubach's No. 25 Duplex tablets*, 3 drums containing 41,000 tablets of *Private Formula No. 204308 tablets*, and 5 65-tablet boxes of *Laubach's No. 15 tablets* at Jersey City, N.J., in possession of Laubach Proprietary Medicines, Inc.

SHIPPED: Between 3–26–56 and 11–1–56, from Worcester, Mass., and Philadelphia, Pa.

LABEL IN PART: (Drum) "Private Formula * * * Spec. #204291 * * * Lot No. 39034 * * * Each tablet contains: Sodium Salicylate 5 gr. * * * Buchu 1 gr. Resin Guaiac Powder 2 gr."; (box) "Contents 25 White and 25 Pink Tablets Laubach's No. 25 Duplex Tablets White Tablet—sodium salicylate, Buchu, Guaiacum (resin) Pink Tablets—Sodium Bicarbonate"; (drum) "Private Formula * * * Spec. #204308 * * * Each tablet contains: Magnesium Oxide (2 gr.) 0.12 Gm. Sodium Bicarbonate (3 gr.) 0.2 Gm. Calcium Carbonate (2 gr.) 0.12 Gm. Bismuth Subcarbonate (5 gr.) 0.3 Gm. Saccharin 0/1000 Gr. Oil of Peppermint 1/20 Gr."; (box) "Contents 65 Tablets Laubach's No. 15 Tablets Bismuth Subcarbonate, Magnesia, Calcined, Sodium Bicarbonate, Calcium Carbonate"; and (btl.) "Compressed tablets * * * Sodium Bicarbonate * * * 10 grains."

*See also Nos. 5562, 5568–5576.

ACCOMPANYING LABELING: Placard reading, in part, "Laubach's Medicines * * * Laubach's No. 15 Tablets," leaflet entitled "Laubach's Medicines for Stomach Disorders," and booklets entitled "Are You Suffering From Acid Stomach—Gastric Ulcers."

RESULTS OF INVESTIGATION: The tablets in the 30-box lot were repacked from the 2-drum and 9-bottle lots, and the tablets in the 5-box lot were repacked from the 3-drum lot. The accompanying labeling was printed locally for the consignee.

LIBELED: 6–21–57, Dist. N.J.

CHARGE: 502(a)—the labeling accompanying the articles, while held for sale, contained false and misleading representations that *Laubach's No. 25 Duplex tablets* were an adequate and effective treatment for acute rheumatic fever, muscular aches, pains, gout, and muscular lumbago, and that *Laubach's No. 15 tablets* were an adequate and effective treatment for stomach disorders, including stomach ulcers.

DISPOSITION: 9–3–57. Consent—claimed by Laubach Proprietary Medicines, Inc., Jersey City, N.J., and relabeled.

5580. Listerine. (F.D.C. No. 40843. S. Nos. 60–746 M, 61–355 M, 75–869 M, 76–153 M, 76–289 M, 76–625 M.)

QUANTITY: 89 14-oz. btls., 88 7-oz. btls., and 114 3-oz. btls., and 23 cases, 12 14-oz. btls. each, 135 cases, 12 7-oz. btls. each, and 87 cases, 48 3-oz. btls. each, at Boston, Mass.

SHIPPED: At various times, including 8–14–57, from Lititz, Pa., by Lambert-Hudnut.

LABEL IN PART: (Btl. wrapper) "Listerine Antiseptic * * * Alcohol 25% Active Ingredients: Thymol, eucalyptol, methyl salicylate, menthol, benzoic acid and boric acid Lambert Pharmacal Company * * * St. Louis, Mo."

ACCOMPANYING LABELING: Placard headed: "A Timely Warning."

LIBELED: 10–14–57, Dist. Mass.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was effective for preventing Asian influenza.

DISPOSITION: 3–10–58. Default—delivered to charitable institutions for their use and not for sale.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U.S. GOVERNMENT PRINTING OFFICE: 1959

D.D.N.J., F.D.C. 5581–5620 Issued October 1959

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5581–5620

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve seizure proceedings in which decrees of condemnation were entered after default or consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *October 15, 1959.*

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*For presence of a habit-forming substance without warning statement, see No. 5584; omission of, or unsatisfactory, ingredients statements, Nos. 5584, 5594, 5607; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 5584, 5607; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5584.

524301—59——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5581–5620

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia and National Formulary), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength and quality differed from that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 502(f)(2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5581. Clarimycin. (F.D.C. No. 41325. S. No. 83–423 M.)

QUANTITY: 35 display cartons, each containing 6 btls., at Columbus, Ohio.

SHIPPED: 11–22–57, from Jersey City, N.J., by Merritt Corp.

LABEL IN PART: (Btl.) "5 drams Clarimycin Anti-Biotic Acne Lotion * * * Active ingredients: Neomycin Sulphate, Allantoin."

LIBELED: 1–7–58, S. Dist. Ohio.

CHARGE: 505(a)—The article, when shipped, was a new drug which may not be shipped in interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 8–20–58. Consent—destruction.

5582. Clarimycin. (F.D.C. No. 41372. S. No. 60–378 M.)

QUANTITY: 366 display cards, each containing 1 btl., at Detroit, Mich.

SHIPPED: 11–25–57, from Jersey City, N.J., by Merritt Corp.

LABEL IN PART: (Btl.) "Contents: 5 drams Clarimycin Anti-Biotic Acne Lotion * * * Active Ingredients: Neomycin Sulphate, Allantoin."

LIBELED: 1–22–58, E. Dist. Mich.

CHARGE: 505(a)—the article, when shipped, was a new drug which may not be shipped in interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: Merritt Corp., claimant, having filed a motion for consolidation and removal, the court, on 5–16–58, after consideration of the briefs of the parties, handed down the following opinion in denial of the motion:

O'SULLIVAN, *District Judge:* "This cause is before the Court upon motion of Merritt Corporation to consolidate this cause with cause No. 17780, also pending in this court, Civil Action 5184 pending in the United States District Court for the District of Ohio, Eastern Division, and cause No. 16750, pending in the United States District Court for the Western District of Pennsylvania, and to remove the cases so consolidated for trial in the Southern District of New York. After due consideration thereof, the Court does find and order as follows:

"1) The claimant, Merritt Corporation, claims that its motion has validity by reason of the provisions of 21 USC 334(a) and 21 USC 334(b), or if not entitled to have its motion granted under those two statutes, then under 28 USC 1404(a) or 28 USC 1404(b).

"2) The Government's libel is bottomed upon its claim that the articles subject to the libel constitute a new drug and that there is no statutory authority for this Court in such case to remove or consolidate the causes mentioned, by virtue of the above-mentioned statutes. The Court so finds.

"3) Claimant asserts that the cause pending in the District Court of Pennsylvania is, in effect, a misbranding case which would authorize the removal sought. If such is true, then a motion might well be addressed to the Pennsylvania District Court to remove that cause to the Southern District of New York, and the other causes pending in Michigan and Ohio might well be held in abeyance pending disposition of the Pennsylvania cause so removed to New York.

"NOW, THEREFORE, it is hereby Ordered that the motion of Merritt Corporation to consolidate and remove the mentioned causes may be, and it is, denied."

On 8–27–58, the claimant having consented, the court entered a decree of condemnation and ordered that the product be destroyed.

5583. Royal jelly capsules. (F.D.C. No. 40945. S. No. 69–118 M.)

QUANTITY: 500 capsules, each containing 50 mg., of *royal jelly* at New York, N.Y., in possession of Reid & Cubit, Inc.

SHIPPED: 9–10–57, from Linden, N.J.

LABEL IN PART: "This Royal Jelly from selected queen cells is not more than two days old after introducing the larvae which gives the most active concentration."

ACCOMPANYING LABELING: Printed matter designated "Reprints of Scientific News Reports on Royal Jelly."

RESULTS OF INVESTIGATION: The article was shipped as described above in bulk containers and, upon receipt at New York, N.Y., it was repackaged into small vials and relabeled by the dealer as above described.

LIBELED: 12–10–57, S. Dist. N.Y.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article would sexually rejuvenate, increase the life span, and give a lift to the aged and infants; and 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to law was not effective with respect to the article.

DISPOSITION: 1–6–58. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5584. Various drugs. (F.D.C. No. 40985. S. Nos. 79–421 M, 79–423/4 M, 79–426/9 M.)

QUANTITY: 10 vials of *Suavitil benactyzine hydrochloride tablets*, 700 tablets of *Belladenal* in an unlabeled btl., 1 700-tablet labeled btl. of *Doriden*, 1 800-tablet btl. of *Metamine with butabarbital*, 1 850-tablet btl. of *Ritalin*, 1 1,000-tablet btl. of *Plimasin*, and 7 100-tablet btls. of *Premarin*, at Jersey City, N.J., in possession of Carl H. Kaplan Sales Co.

SHIPPED: Between November 1956 and October 1957, from Rouses Point, Yonkers, and New York, N.Y.

RESULTS OF INVESTIGATION: The articles, except for the *Premarin tablets*, consisted of physicians' samples which the consignee, Carl H. Kaplan Sales Co., had obtained from various drug salesmen, drug firms, and unknown sources, and had transported to Jersey City. All of the articles, including the *Premarin tablets*, were repacked and relabeled after receipt by the consignee.

LIBELED: 12–2–57, Dist. N.J.

CHARGE: 502(b)—while held for sale, the labels of the *Suavitil benactyzine hydrochloride tablets*, *Belladenal tablets*, *Doriden tablets*, *Metamine with butabarbital tablets*, and *Plimasin tablets* failed to bear (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(d)—the *Belladenal tablets* and *Metamine with butabarbital tablets* contained chemical derivatives of barbituric acid, and while held for sale, their labels failed to bear the name, and quantity or proportion of such dervative and in juxtaposition therewith the statement "Warning—May be habit forming"; 502(e)(2)—the label of the *Belladenal tablets*, while held for sale, failed to bear a statement of the quantity or proportion of the alkaloids of belladonna contained therein; 502(f)(1)—while held for sale, the labeling of the *Suavitil benactyzine hydrochloride tablets*, *Belladenal tablets*, *Doriden tablets*, and *Metamine with butabarbital tablets* failed to bear adequate directions for use; and 503(b)(4)—all of the articles were drugs subject to 503(b)(1), and the labels of the articles, while held for sale, failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The libel alleged also that an article labeled "Obron" was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1–15–58. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5585. Super Protein Formula "90" and Formula "90" Supplement. (F.D.C. No. 41434. S. No. 75–649 M.)

QUANTITY: 7 pkgs. containing 1 btl. of *Super Protein Formula "90"* and 1 btl. of *Formula "90" Supplement* at Phoenix, Ariz.

SHIPPED: 7–10–57, from Hollywood, Calif., by Hi-Pro Products Co.

LABEL IN PART: (Btl.) "MpDs * * * Super Protein Formula '90' An aid to Weight Reducing Increases Energy – Helps Reduce Weight * * * MpDs is a Balanced Protein Food Supplement Contains No Calories * * * 180

*See also No. 5584.

[or '360'] tablets" and "Formula '90' Supplement Reducing * * * 15 Capsules * * * an additional aid to weight reducing – to be taken in conjunction with MpDs Super Protein Tablets * * * Each Tablet Contains: Sodium Carboxy Methyl Cellulose . . . . 8 grains Phenylasitin (conc. Prune) . . . 0.5 Mg."

ACCOMPANYING LABELING: Booklets entitled "Why Be Fat."

LIBELED: 3–5–58, Dist. Ariz.

CHARGE: 502(a)—the labeling of the *Super Protein Formula "90"* and the *Formula "90" Supplement*, when shipped, contain false and misleading representations that the articles contained no calories, would burn up extra fat, increase metabolism, and otherwise act as an adequate and effective treatment for obesity; and 502(f)(2)—the *Formula "90" Supplement* contained an irritant laxative, and its labeling failed to warn that it should not be used when symptoms of appendicitis were present and that frequent or continued use may result in dependence on laxatives.

DISPOSITION: 5–7–58. Default—destruction.

5586. Trim-All capsules. (F.D.C. No. 41453. S. No. 23–306 P.)

QUANTITY: 3 drums containing a total of 41,500 capsules at North Hollywood, Calif.

SHIPPED: 11–6–57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABELED IN PART: (Drum) "Lot No. 3218 * * * Special Formula #2 * * * Each capsule contains 60 mg. Phenylpropanolamine Hcl. 3 gr. Sodium Caseinate, 50 mg. Ascorbic Acid, 0.5 mg. Acetphenolisatin."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 77 percent of the labeled amount of phenylpropanolamine Hcl and 64 percent of the labeled amount of ascorbic acid, of which the article released 90 percent of both in 2 hours. The article was intended to be repackaged and relabeled by the consignee as follows: "21 Trim-All Capsules (an Appetite Depressant) Each Trim-All Timed Capsule Contains: Phenylpropanolamine Hcl 60 mg. Sodium Caseinate 3 gr. Dextrose 3 gr. Ascorbic acid 50 mg. Acetphenolisatin 0.5 mg. In a specially prepared Timed disintegrating capsule that releases the ingredients over a period of approximately eight hours.

LIBELED: 3–6–58, S. Dist. Calif.

CHARGE: 501(c)—when shipped, the strength of the article differed from, and its quality fell below, that which it purported or was represented to possess since it contained less than the labeled amounts of phenylpropanolamine Hcl and ascorbic acid, and it failed to release its ingredients over an 8-hour period; 502(a)—the label statements of the article, when shipped and while held for sale, namely, "Each capsule contains 60 mg. Phenylpropanolamine Hcl. * * * 50 mg. Ascorbic Acid" and "Each Trim-All Timed Capsule Contains: Phenylpropanolamine Hcl 60 mg. * * * Ascorbic acid 50 mg. * * * In a specially prepared Timed disintegrating capsule that releases the ingredients over a period of approximately eight hours," were false and misleading; and 502(f)(2)—the article was a laxative, and its labeling, when shipped and while held for sale, failed to warn against use when symptoms of appendicitis are present and that frequent or continued use may result in dependence on laxatives.

DISPOSITION: 3–26–58. Default—destruction.

5587. Salicon tablets. (F.D.C. No. 40953. S. No. 76–626 M.)

QUANTITY: 135 100-tablet btls., 61 30-tablet btls., and 60 12-tablet btls. at Portland, Maine.

SHIPPED: 9–30–57, from Boston, Mass., by K. A. Hughes Co.

LABEL IN PART: "Salicon * * * 5 Grain Tablets Active Ingredients: Acetylsalicylic acid (U.S.P. Aspirin) calcium carbonate and magnesium carbonate."

LIBELED: 11–14–57, Dist. Maine.

CHARGE: 502(a)—when shipped, the label of the article contained false and misleading representations that the article was an adequate and effective treatment for nervous tension and sleeplessness; 502(f)(1)—the labeling of the article failed to bear adequate directions for use since, in lieu of a dosage statement for children under 3 years of age, its labeling failed to state that for the 3 year and under age group a physician should be consulted; and 502(f)(2)—its labeling failed to bear a warning against misuse by children since its labeling failed to warn that the product should be kept out of reach of children.

DISPOSITION: 1–7–58. Default—destruction.

5588. Zina-Ray oil, inhalers, and Ten Second Rub. (F.D.C. No. 41449. S. No. 24–906 P.)

QUANTITY: 1,080 1-oz. btls. and 284 3-oz. btls. of *Zina-Ray oil*, 26 cartons, each containing 1 gross of *inhalers*, and 1,065 1-oz. tubes and 265 3-oz. tubes of *Ten Second Rub* at Minneapolis, Minn., in possession of William R. Hall.

SHIPPED: Between 1–7–58 and 1–21–58, from Chicago, Ill.

LABEL IN PART: (Btl.) "Zina-Ray Oil * * * Contains eucalyptus oil, menthol, pine needle oil, peppermint oil"; (vial) "Inhaler Directions: Insert a few drops of * * * Zina-Ray Oil into the end of inhaler"; and (tube) "Ten Second Rub * * * Active ingredients: Lanolin, menthol, eucalyptus oil, peppermint oil, and pine needle oil."

LIBELED: 3–7–58, Dist. Minn.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, namely, (*Zina-Ray oil* and *inhalers*) for preventing headache, pain in the gums, neuralgia, deafness, arthritis, rheumatism, formation of crystal deposits in the bones, inflammation of the ear, pneumonia, "flu", and overcoming sinus infection and asthma, and (*Ten Second Rub*) for overcoming arthritis, rheumatism, and all aches and pains to which the body is subject, which were the purposes for which the articles were recommended orally by William R. Hall on 1–23–58.

DISPOSITION: 4–21–58. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5589. Chorionic gonadotropin. (F.D.C. No. 41363. S. No. 68–979 M.)

QUANTITY: 1,758 vials at New York, N.Y.

SHIPPED: 7–1–57, from Orange, N.J.

RESULTS OF INVESTIGATION: Examination showed that the article contained substantially less than 2,500 International Units of chorionic gonadotropin potency per vial.

LIBELED: 1–21–58, S. Dist. N.Y.

*See also No. 5586.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it was represented to possess, namely, 2,500 International Units of chorionic gonadotropin potency per vial; and 502(a)—the label statement "When reconstituted with 10 ml. diluent each vial will contain: Chorionic Gonadotropin 2500 IU" was false and misleading.

DISPOSITION: 2–20–58. Default—destruction.

5590. Chorionic gonadotropin. (F.D.C. No. 41467. S. No. 85–243 M.)

QUANTITY: 261 vials at Chicago, Ill.

SHIPPED: 10–11–57, from Orange, N.J.

RESULTS OF INVESTIGATION: Examination showed that the article contained substantially less than the 2,500 International Units of chorionic gonadotropin potency per vial which it was represented to have.

LIBELED: 3–10–58, N. Dist. Ill.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it was represented to possess, namely, 2,500 International Units of chorionic gonadotropin potency per vial.

DISPOSITION: 4–14–58. Default—destruction.

5591. Reserpine injection. (F.D.C. No. 40420. S. No. 72–560 M.)

QUANTITY: 2,718 ampuls at Milwaukee, Wis.

SHIPPED: 7–5–56, from Detroit, Mich.

RESULTS OF INVESTIGATION: Analysis showed that the article contained 83 percent of the declared amount of reserpine.

LIBELED: 8–14–57, E. Dist. Wis.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported or was represented to possess, namely, 2.5 mg. per cubic centimeter; and 502(a)—the label statement "2.5 mg. per cc" was false and misleading as applied to the article, which contained less than the declared amount of reserpine per cubic centimeter.

DISPOSITION: 1–27–58. Consent—destruction.

5592. Cowlserpa tablets. (F.D.C. No. 40994. S. No. 64–348 M.)

QUANTITY: 19 1,000-tablet btls. at Buffalo, N.Y.

SHIPPED: 7–19–57, from Auburn, Mass., by Cowley Pharmaceuticals.

RESULTS OF INVESTIGATION: Examination showed that the article contained 81 percent of the labeled amount of reserpine.

LIBELED: 11–18–57, W. Dist. N.Y.; Amended libel, 12–11–57.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; and 502(a)—the label statement "Each Tablet Contains: Reserpine 0.25 mg." was false and misleading.

DISPOSITION: 1–15–58. Default—destruction.

5593. Phenobarbital capsules. (F.D.C. No. 41203. S. No. 55–960 M.)

QUANTITY: 9,000 capsules in btls. at Muncie, Ind.

SHIPPED: 5–3–57, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: "List No. Time-Sule Phenobarbital 1 Gr. * * * 1,000 Capsules Control No. 1586."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 77 percent of the declared amount of phenobarbital.

LIBELED: 12–4–57, S. Dist. Ind.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 1 grain of phenobarbital per capsule; and 502(a)—the label statement "Time-Sule Phenobarbital 1 Gr." was false and misleading.

DISPOSITION: 2–28–58. Default—destruction.

5594. Tran-quil-eez tablets. (2 seizure actions). (F.D.C. Nos. 41374, 41375. S. Nos. 57–528 M, 77–788 M.)

QUANTITY: 23 pkgs., each containing 6 ctns. enclosing a 30-tablet pill box, at St. Petersburg, Fla., and 43 ctns., each containing 1 pill box, at Miami, Fla.

SHIPPED: 9–19–57 and 10–19–57, from Cincinnati, Ohio, by Grandpa Soap Co. and C. S. Dent & Co., Div. Grandpa Soap Co.

LABEL IN PART: (Ctn.) "Dent's Tran-quil-eez 30 Tablets * * * Each enteric-coated tablet contains: Theobromine Sodium Salicylate 100 mg. Acetylsalicylic Acid 3 gr. Acetophenetidin 2 gr. * * * Distributed by C. S. Dent & Co., Cincinnati 2, Ohio."

ACCOMPANYING LABELING: Circulars reading in part "Personal for Women Only Take Free Leaflet" and package insert reading in part "to end those Blue Days * * * Dent's Tran-quil-eez."

LIBELED: 1–23–58 and 1–27–58, S. Dist. Fla.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported or was represented to possess since it contained a significantly lesser quantity of acetylsalicylic acid (aspirin) than the amount stated on the label; 502(a)—the label statement "Acetylsalicylic Acid 3 Gr." was false and misleading; 502(a)—the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for overcoming "nerve-racking pre-menstrual symptoms," overcoming effects such as nervous tension and irritability due to extra fluids which alter the water balance in the brain, overcoming pressure exerted by fluids on various parts of the body which result in a heavy, swelling feeling which robs one of looks and vitality and causes the face to become puffy, the hands and fingers to swell up, and causing pain in the back, legs, and breasts, eliminating "those terrible pressures that make you so uncomfortable, nervous and irritable at the onset of your period," and "preparing the body physiologically for the menstrual period"; and 502(e)(2)—the label of the article failed to bear the common or usual name of the active ingredient listed as acetylsalicylic acid, for which the common or usual name is aspirin.

DISPOSITION: 4–9–58 and 4–14–58. Default—destruction.

5595. Del-Caps capsules and Del-Bardex capsules. (F.D.C. No. 41431. S. Nos. 34–042/3 P.)

QUANTITY: 1 9,900-capsule drum, 1 49,900-capsule drum, 8 1,000-capsule btls., 7 500-capsule btls., and 42 100-capsule btls., of *Del-Caps*, and 1 25,000-capsule drum, 3 500-capsule btls., and 7 100-capsule btls. of *Del-Bardex* at Philadelphia, Pa.

SHIPPED: 11–5–57 and 11–27–57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: (Drum) "Del-Caps 15 Timed Disintegration Capsule * * * Each capsule contains 15 mg. of Dextro-Amphetamine Sulfate in a special base that provides for the disintegration of the contents throughout a period of 6–10 hours * * * 3259" and "Del-Bardex #2 Timed Disintegration Capsule Each Capsule Contains Dextro-Amphetamine Sulfate 15 Mg. Amobarbital 100 Mg. * * * Each capsule contains 15 Mg. of Dextro-Amphetamine Sulfate * * * in a special base that provides for the disintegration of the contents throughout a period of about 6–10 hours * * * 3100."

RESULTS OF INVESTIGATION: The capsules in the btls. had been repacked from the above-mentioned drums by the consignee after shipment.

Analysis showed that the *Del-Caps capsules* released 94 percent of their dextro-amphetamine sulfate content in 2 hours and that the *Del-Bardex capsules* released 80 percent of their dextro-amphetamine sulfate content in 2 hours.

LIBELED: 2–17–58, E. Dist. Pa.

CHARGE: 501(c)—the quality of the articles, when shipped, differed from that which they purported or were represented to possess in that they failed to disintegrate at a uniform rate over a 6- to 10-hour period; and 502(a)—the labels contained false and misleading representations that the dextro-amphetamine sulfate content of the articles would be released at a uniform rate over a 6- to 10-hour period.

DISPOSITION: 3–27–58. Default—destruction.

5596. Del-Bardex capsules. (F.D.C. No. 41491. S. No. 29–803 P.)

QUANTITY: 4 drums containing a total of 98,000 capsules at Jersey City, N.J.

SHIPPED: 12–17–57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: "Del-Bardex # 2 Timed Disintegration Capsule Each Capsule Contains: Dextro-Amphetamine Sulphate 15 Mg. Amobarbital 100 Mg. * * * disintegration * * * period of about 6–10 hours."

RESULTS OF INVESTIGATION: Analysis showed that 90 percent of the dextro-amphetamine sulfate content of the article was released in 2 hours.

LIBELED: 3–28–58, Dist. N.J.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess since it failed to disintegrate at a uniform rate over a 6- to 10-hour period; and 502(a)—the label statement "disintegration * * * period of about 6–10 hours" was false and misleading.

DISPOSITION: 4–28–58. Default—destruction.

5597. S.C. red pyrilamine maleate tablets. (F.D.C. No. 40995. S. No. 80–326 M.)

QUANTITY: 1 case containing 10,000 tablets at Minneapolis, Minn.

SHIPPED: 8–29–57, from St. Louis, Mo.

RESULTS OF INVESTIGATION: Examination showed that the article had a strong odor of acetic acid, contained large cracks in its coating due to bursting, and contained a significant amount of free salicylic acid.

LIBELED: 11–22–57, Dist. Minn.

CHARGE: 501(c)—the quality of the article, while held for sale, fell below that which it purported and was represented to possess since the tablet coatings were bursting and the aspirin was decomposing.

DISPOSITION: 1–6–58. Default—destruction.

5598. Pentanitrol tablets. (F.D.C. No. 41389. S. No. 20–962 P.)

QUANTITY: 8 500-tablet btls. at Kansas City, Kans.

SHIPPED: 1–13–58, from Chicago, Ill., by Kasar Co.

LABEL IN PART: "Tablets Pentanitrol Pentaerythritol Tetranitrate 10 Mg."

RESULTS OF INVESTIGATION: Examination showed that the article contained 20 mg. of pentaerythritol tetranitrate per tablet.

LIBELED: 2–4–58, Dist. Kans.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 10 mg. of pentaerythritol tetranitrate; and 502(a)—the label statement "Pentaerythritol Tetranitrate 10 Mg." was false and misleading.

DISPOSITION: 3–18–58. Default—destruction.

5599. Halazone tablets. (F.D.C. No. 41443. S. No. 29–863 P.)

QUANTITY: 44 cases, each containing 100 btls., at Brooklyn, N.Y.

SHIPPED: About 1955, from Atlanta, Ga.

LABEL IN PART: (Btl.) "100 Water Purification Tablets For Purifying Drinking Water in Canteens * * * Halazone N.N.R. * * * Each tablet contains 0.004 Gm. (1/16 grain) of Halazone with sodium borate and chloride."

RESULTS OF INVESTIGATION: Examination showed that the article contained from 42 to 73 percent of the labeled amount of halazone.

LIBELED: 3–3–58, E. Dist. N.Y.

CHARGE: 501(b)—the strength of the article, while held for sale, differed from the standard for halazone tablets set forth in the National Formulary.

DISPOSITION: 3–20–58. Default—destruction.

5600. Triferon iron and vitamin tablets and Triferon compound tablets. (F.D.C. No. 41416. S. Nos. 3–481/2 P.)

QUANTITY: 1 drum containing 48,050 *Triferon iron and vitamin tablets* and 1 drum containing 21,620 *Triferon compound tablets* at Silver Spring, Md.

SHIPPED: Prior to 12–31–54, from Brooklyn, N.Y.

RESULTS OF INVESTIGATION: Analysis showed that the *Triferon iron and vitamin tablets* contained less than 70 percent of the declared amount of vitamin B_1 and that the *Triferon compound tablets* contained less than 50 percent of the declared amount of vitamin B_1 (thiamine Hcl).

LIBELED: 2–7–58, Dist. Md.

CHARGE: 501(c)—the strength of the articles, while held for sale, differed from that which they purported and were represented to possess; and 502(a)—the label statements "Triferon – Iron & Vitamin Tablets * * * Each Tablet Contains * * * Thiamin HCl 1.5 mg." and "Triferon CPD * * * Each Tablet Contains: * * * Thiamin Hcl 0.5 mg." were false and misleading.

DISPOSITION: 4–24–58. Default—destruction.

5601. Beta Foplex, MRT Concentrate. (F.D.C. No. 41417. S. No. 29–843 P.)

QUANTITY: 18 btls. at Brooklyn, N.Y.

SHIPPED: 12–13–57, from Stamford, Conn., by Marvin R. Thompson, Inc.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 60 percent of the declared amount of riboflavin.

LIBELED: 2–17–58, E, Dist. N.Y.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; and 502(a)—the label statement "One cc * * * contains: * * *Riboflavin (Vitamin B_2) . . . . 2.0 mg." was false and misleading.

DISPOSITION: 3–19–58. Default—destruction.

5602. Olive oil. (F.D.C. No. 41246. S. No. 59–665 M.)

QUANTITY: 264 bottles at Gary, Ind.

SHIPPED: 10–30–57, from Nashville, Tenn., by National Co.

LABEL IN PART: "Contents 2 Fl. Oz. * * * Pure Imported Olive Oil For Table and Medicinal Use."

RESULTS OF INVESTIGATION: Examination of the article disclosed the presence of camphorated oil, a poisonous and deleterious substance.

LIBELED: 12–26–57, N. Dist. Ind.

CHARGE: 501(b)—when shipped, the article purported to be U.S.P. olive oil, a drug the name of which is recognized in the United States Pharmacopeia, and the quality of the article fell below the standard for olive oil set forth in the Pharmacopeia.

The article was alleged also to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 2–11–58. Default—destruction.

5603. Rubber prophylactics. (F.D.C. No. 41311. S. No. 85–133 M.)

QUANTITY: 349 ctns., each containing 144 2-unit pkgs., at Chicago, Ill.

SHIPPED: 10–11–57, from St. Louis, Mo., by M & M Rubber Co.

LABEL IN PART: "Spartans Prophylactics."

RESULTS OF INVESTIGATION: Examination showed that 4 out of 216 units examined were defective in that they contained holes.

LIBELED: 12–30–57, N. Dist. Ill.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported to possess; and 502(a)—the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: 1–21–58. Consent—claimed by M & M Rubber Co. Segregated; 42 gross denatured for use as scrap rubber.

5604. Skin prophylactics. (F.D.C. No. 41005. S. No. 86–518 M.)

QUANTITY: 20 gross of *prophylactics* at North Kansas City, Mo.

SHIPPED: 11–6–57, from Chicago, Ill., by Frank G. Karg.

LABEL IN PART: "Peacock's Redi-Wet Slip-on Skin."

RESULTS OF INVESTIGATION: Examination showed that 16 percent of the article was defective in that it contained holes.

LIBELED: On or about 11–21–57, W. Dist. Mo.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported to possess.

DISPOSITION: 1–16–58. Default—destruction.

5605. Rubber prophylactics. (F.D.C. No. 40919. S. No. 79–604 M.)

QUANTITY: 16 ctns., each containing 7,200 individual *rubber prophylactics*, at New York, N.Y.

SHIPPED: 12–31–56, from Akron, Ohio, by Killashun Sales Division.

LABEL IN PART: (Ctn.) "3 Axne * * * 1 * * * Tubed 3 * * * Knights"; (prophylactic) "Three Knights Sold For Prevention of Disease Only * * * Made in U.S.A. C–1–57."

RESULTS OF INVESTIGATION: Examination showed that 2.5 percent of the article was defective in that it contained holes.

LIBELED: 11–18–57, S. Dist. N.Y.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported to possess; and 502(a)—the label statement "Sold For Prevention of Disease Only" was false and misleading as applied to an article containing holes.

DISPOSITION: 3–5–58. Consent—claimed by Akwell Corp., Akron, Ohio, and destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

5606. Edwards Super Caps, Drugmaster cough syrup, and Sperry's cabbage juice tablets. (F.D.C. No. 41477. S. Nos. 25–426/8 P.)

QUANTITY: 22 15-tablet vials of *Edwards Super Caps*. 26 4-oz btls. and 21 8-oz. btls. of *Drugmaster cough syrup*, and 12 100-tablet btls. of *Sperry's cabbage juice tablets* at Milbank, S. Dak., in possession of Edwards Jewelry & Drugs.

SHIPPED: Between 1–25–56 and 12–5–57, from Des Moines, Iowa, St. Louis, Mo., and Hollywood, Fla.

LABEL IN PART: (Btls.) "Edwards Super Caps * * * 15 Tab Capsules * * * Hesperidin (Citrus Bioflavonoid) 50 mg. Pyrilamine Maleate 25 mg. Ascorbic Acid 50 mg. Aspirin 4 gr. Phenacetin 2 gr. Caffeine .25 gr. per Tab-Capsule," "Sperry's Cabbage Juice Tablets Raw Cabbage Juice Dehydrated without heat * * * 100 Tablets * * * Contains: Freshly extracted cabbage juice dried with calcium carbonate, skim milk solids, papain, aluminum hydroxide and oyster shell powder," and "Drugmaster Hista-Pro Antihistamine with Vitamin C Cough Syrup Active Ingredients per 5 cc. Ammonium Chloride 60 mg. Sodium Citrate 135 mg. Methapyrilene Fumerate 6.25 mg. Ascorbic Acid 12 mg. Sodium Benzoate 0.1%."

ACCOMPANYING LABELING: Window posters reading "Asian Flu Capsules—For Prompt Results," placard reading "Asian Flu Fast Acting Capsules," and placards reading, in part, "Upset Stomach Ulcers Use Compound Tablets of Cabbage Juice Extract."

RESULTS OF INVESTIGATION: The above-mentioned posters and placard were printed locally for the dealer.

LIBELED: 3–27–58, Dist. S. Dak.

CHARGE: 502(a)—the labeling of the articles, while held for sale, contained false and misleading representations that the *Edward Super Caps* were an adequate and effective treatment for Asian "flu," sinus colds, and grippe; that the *Drugmaster cough syrup* was effective in the treatment of Asian "flu"; and that the *Sperry's cabbage juice tablets* were an adequate and effective treatment for stomach ulcers.

DISPOSITION: 5–5–58. Consent—destruction.

*See also Nos. 5583, 5585–5587, 5589, 5591–5596, 5598, 5600, 5603, 5605.

5607. Nerv-Aid capsules. (F.D.C. No. 41432. S. No. 21–065 P.)

QUANTITY: 5,784 10-capsule btls. at North Kansas City, Mo.

SHIPPED: Between 1–3–58 and 1–24–58, from Memphis, Tenn., by Keystone Laboratories, Inc.

LABEL IN PART: "Nerv-Aid * * * Each capsule contains: Sodium Bromide 4 grs. Potassium Bromide 4 grs. Ammonium Bromide ½ gr. Methapyrilene Hydrochloride 25 mgs."

ACCOMPANYING LABELING: Leaflet reading in part "Can't seem to concentrate . . . can't sleep at night . . . suffer vague aches and pains . . . Read the truth about Your Nerves . . . And *You* by Dr. Paul J. Morgan, Ph. D."

LIBELED: 2–19–58, W. Dist. Mo.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was effective in the prevention or treatment of chronic headaches, depression, fear, inability to concentrate, dizzy spells, nervous stomach, peptic ulcers, irritable colon, vomiting, diarrhea, racing pulse, pounding heart, profuse sweating, heavy breathing, fear of disease, suffering, and death, and uncontrollable appetite; 502(b)(2)—the ctn. label failed to bear an accurate statement of the quantity of contents (the ctn. label bore no statement of the quantity of contents); and 502(e)(2)— the ctn. label failed to bear the common or usual name of each active ingredient of the article (the ctn. label bore no ingredient statement).

DISPOSITION: 5–16–58. Default—destruction.

5608. Dyn-R-Gy tablets. (F.D.C. No. 41290. S. No. 76–303 M.)

QUANTITY: 71 cases, each containg 36 ctns., each ctn. containing 4 100-tablet btls., at Needham, Mass., in possession of Jensen Laboratories, Inc.

SHIPPED: 9–17–57, from Philadelphia, Pa., by J. W. B. Delavau Co., Inc.

LABEL IN PART: "Dyn-R-Gy * * * Each tablet contains: Ascorbic Acid 10 mg. Calcium Gluconate 120 mg. Sodium Chloride 50 mg. Potassium Chloride 5 mg. Thiamine Chloride 5 mg. Potassium Sulfate 2 mg. Magnesium Phosphate 1 mg. Citric Acid 10 mg. Dextrose 175 mg."

ACCOMPANYING LABELING: Display placards reading in part "New Dyn-R-Gy restores energy! Dyn-R-Gy works quickly to revive vitality naturally!"; a window streamer entitled "Naturally We Have Dyn-R-Gy"; and a brochure entitled "Dyn-R-Gy."

RESULTS OF INVESTIGATION: The placards were printed locally for the consignee, and the window streamer and brochure were prepared in Boston, Mass., for use in promoting the sale of the article.

LIBELED: 12–13–57, Dist. Mass.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for fatique and exhaustion; that it would eliminate that "tired, worn-out feeling"; that it would revive one's vitality and restore one's energy; and for the improvement of body functions, tissue formation, osteoporosis, dental caries, capillary fragility, muscular cramps, allergic reactions, and for prevention of neuroses.

DISPOSITION: 3–17–58. Default—destruction.

5609. Gelatin Glory capsules. (F.D.C. No. 41465. S. Nos 25–207/8 P.)

QUANTITY: 182 boxes, each containing 90 capsules, and 5 boxes, each containing 201 capsules, at Minneapolis, Minn.

SHIPPED: 1–24–58, from Santa Monica, Calif., by Gelatin Plus Co.

LABEL IN PART: "Gelatin Glory For Problem Hair 90 [or "201"] Ten Gr. Capsules A Dietary Supplement * * * Each capsule contains Vitamin B_1 * * * 1.2 mg. Niacinamide 10.0 mg. Vitamin B_2 * * * 1.2 mg. Calcium Pantothenate 2.5 mg. Vitamin B_6 * * * 0.33 mg. Para-Aminobenzoic Acid 100.0 mg. Vitamin B_{12} * * * 0.33 mcg. Yeast 400.0 mg. Gelatin 1.2 gm. Plus all other vitamin B complex factors naturally occurring in yeast * * * Directions: One capsule with meals, three times daily."

ACCOMPANYING LABELING: Leaflet entitled "Gelatin Glory Hair Health and Beauty . . . in a Capsule."

LIBELED: 3–13–58, Dist. Minn.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for reconditioning dry and brittle hair, restoring life and natural color to hair, and producing healthy and beautiful hair.

DISPOSITION: 5–5–58. Consent—claimed by Gelatin Plus Co. and relabeled.

5610. Multiple vitamins. (F.D.C. No. 40978. S. No. 61–391 M.)

QUANTITY: 6 cases, each containing 6 btls. of 144 tablets each; 4 cases, each containing 12 btls. of 72 tablets each; and 5 cases, each containing 12 btls. of 36 tablets each, at West Hartford, Conn.

SHIPPED: Between 7–8–57 and 9–23–57, from Boston, Mass., by Liggett Drug Co.

LABEL IN PART: (Btl.) "Rexall Super Plenamins plus Red Vitamin B_{12} Multiple Vitamins with minerals Vitamins A–C–D B-Complex – liver concentrate and iron."

ACCOMPANYING LABELING: Window banner reading: "If You Can Build A Resistance Against Asiatic Flu Super Plenamin Vitamins Will Do It Be Safe—Be Sure Start Taking Super Plenamin Vitamin Capsules Today!"

LIBELED: 12–6–57, Dist. Conn.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for preventing Asiatic influenza.

DISPOSITION: 4–18–58. Default—delivered to charitable organizations.

5611. La Vie tablets. (F.D.C. No. 41366. S. No. 78–788 M.)

QUANTITY: 409 105-tablet btls. at New York, N.Y.

SHIPPED: Early in 1956, from Chicago, Ill., by Bates Laboratories, Inc.

LABEL IN PART: (Btl.) "Each Tablet contains: Extract of Galega in an Anise and Tricalcium Base * * * Distributed by La Vie Pharmacal Co., Inc. * * * New York 19, N.Y."

LIBELED: 1–27–58, S. Dist. N.Y.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was effective for increasing the size of the female breasts and making the breasts fuller and firmer.

DISPOSITION: 2–19–58. Default—destruction.

5612. Be-Slim Capettes. (F.D.C. No. 41321. S. Nos. 78–370/1 M.)

QUANTITY: 75 btls. at Oklahoma City, Okla.

SHIPPED: 8–2–57, from Chicago, Ill., by B-Slim Co., Inc.

LABEL IN PART: "Be-Slim T.M. the modern method for Practical Obesity Management * * * 90 Capettes 5556 * * * Each Capette Contains: Phenylpropanolamine hydrochloride 25 mg. Methylcellulose 100 mg. Vitamin A Acetate 1000 U.S.P. Units Vitamin D (Calciferol) 100 U.S.P. Units Thiamin Chloride 2 mg. Riboflavin 1 mg. Pyridoxine HCl 0.1 mg. Niacinamide 10 mg. Folic Acid 0.1 mg. Vitamin B_{12} cobalamin conc. 0.5 megm. Ascorbic Acid 10 mg. Iron (from ferrous sulfate) 3 mg. Calcium (from dicalcium phosphate) 50 mg. Phosphorus (from dicalcium phosphate) 3.75 mg. Iodine (from potassium iodide) 0.5 mg. Fluorine (from calcium fluoride) 0.05 mg. Copper (from copper sulfate) 1 mg. Potassium (from potassium sulfate) 5 mg. Manganese (from manganese sulfate) 1 mg. Zinc (from zinc sulfate) 0.01 mg. Magnesium (from magnesium sulfate) 1 mg. Boron (from sodium borate) 0.05 mg."

ACCOMPANYING LABELING: Leaflets entitled "Be-Slim" and "For the Dealer (or For the Distributor)," survey information cards, and dealers' application sheets.

LIBELED: 1–7–58, W. Dist. Okla.

CHARGE: 502(a)—the name of the article and its labeling, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for obesity.

DISPOSITION: 2–10–58. Default—destruction.

5613. Bu-Methyl pills and Haywood pills. (F.D.C. No. 40335. S. No. 53–170 M.)

QUANTITY: 2 drums, each containing 25,000 *Bu-Methyl pills*, and 60 20-pill btls. and 12 60-pill btls. of *Haywood pills*, at New Orleans, La., in possession of Altone Chemical Co.

SHIPPED: During Dec. 1956, from New York, N.Y.

LABEL IN PART: "Bu-Methyl Pills Each pill contains: Extract Buchu 1 gr. Potassium Bicarbonate 2 gr. Extra Triticum ½ gr. Methylene Blue ½ gr."; (btl.) "Haywood Pills A Diuretic Stimulant for the Kidneys."

ACCOMPANYING LABELING: Circulars headed: "Haywood Pills."

RESULTS OF INVESTIGATION: The pills contained in the btls. were repackaged by the consignee from the above-mentioned bulk drums, which had been shipped as described above. The circulars were prepared locally for the consignee.

LIBELED: 6–24–57, E. Dist. La.

CHARGE: 502(a)—the labeling accompanying the articles, while held for sale, contained false and misleading representations that the articles were effective to flush the millions of miles of kidney tubes, to flush out all waste and poisonous materials that the body couldn't use, to relieve backache, to prevent getting up nights, to overcome loss of sleep, and to furnish pep and energy.

DISPOSITION: 4–8–58. Default—destruction.

5614. Roasted dandelion root and malted and unmalted slippery elm food. (F.D.C. No. 41415. S. Nos. 35–513/5 M.)

QUANTITY: 31 cases, 240 ¼-lb. cans each, of *roasted dandelion root;* 12 cases, 72 1-lb. cans each, of *malted slippery elm food;* and 12 cases, 72 1-lb. cans each, of *unmalted slippery elm food*, at Covington, Ky., in possession of Dandelions Unlimited.

SHIPPED: Between July 1957 and December 1957, from England.

ACCOMPANYING LABELING: Leaflets entitled "Dandelions And You!" "The Story of Thompson's Slippery Elm Food," and counter display cards entitled "Slippery Elm Food."

LIBELED: 2–13–58, E. Dist. Ky.

CHARGE: 502(a)—the labeling accompanying the articles, while held for sale, contained false and misleading representations that the *roasted dandelion root* was an adequate and effective treatment for stimulating the liver and kidneys to improve elimination, cleansing the blood stream to aid in eliminating toxins and other impurities from the system, making eyes and complexion clearer, removing pimples, and strengthening the heart, and that the *slippery elm food, malted and unmalted,* was an adequate and effective treatment for inducing sleep, managing ulcerative conditions and mucous colitis, healing properties, restoring and maintaining health, and for the treatment of inflammation, dysentery, diarrhea, and urinary troubles.

DISPOSITION: 3–8–58. Consent—claimed by Irene E. Barbasch, Covington, Ky., and relabeled.

5615. Wheat germ oil. (F.D.C. No. 41332. S. Nos. 80–445/6 M.)

QUANTITY: 45 100-capsule btls. and 9 200-capsule btls. at Minneapolis, Minn., in possession of Cayol Dietary Foods.

SHIPPED: 10–15–57, from Detroit, Mich.

ACCOMPANYING LABELING: Photostatic copies of a newspaper article entitled "Vitamin E May Halt Heart Attacks."

RESULTS OF INVESTIGATION: The accompanying labeling was displayed in the dealer's store and store windows adjacent to a display of wheat germ oil.

LIBELED: 1–10–58, Dist. Minn.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was effective for preventing heart attacks and hardening of the arteries.

DISPOSITION: 4–12–58. Default—delivered to a charitable institution after destruction of the accompanying labeling.

5616. Isodine gargle. (F.D.C. No. 41430. S. No. 11–275 P.)

QUANTITY: 776 master ctns., each containing 3 ctns. of 12 2-oz. btls. each; 624 ctns. of 12 4-oz. btls. each; and 509 counter display ctns. of 36 4-oz. btls. each at Chicago, Ill.

SHIPPED: Between 11–1–57 and 1–28–58, from Dover, Del., by Isodine Pharmacal Co., and from Cleveland, Ohio, by Strong-Cobb Pharmacal Co.

LABEL IN PART: (Btl. and ctn.) "Isodine Gargle New Safe Iodine Complex * * * Active Ingredients: Polyvinylpyrrolidone-iodine Complex."

LIBELED: 2–17–58, N. Dist. Ill.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for sore throat and sore, bleeding gums.

DISPOSITION: 4–30–58. Consent—claimed by International Latex Corp., Dover, Del., and relabeled.

5617. Sinus and beauty mask and beauty eye mask. (F.D.C. No. 41368. S. No. 49–074 M.)

QUANTITY: 150 *sinus and beauty masks* in ctns. and 50 *beauty eye masks* in ctns. at Chicago, Ill.

SHIPPED: 11-1-57 and 12-20-57, from Quincy, Mass., by Hot-R-Cold Pak, Inc.

LABEL IN PART: (Ctn.) "Hot-R-Cold Sinus and Beauty Mask" and "Beauty Eye-Mask."

RESULTS OF INVESTIGATION: Each article consisted of a pliable plastic container shaped like a masquerade mask so as to cover the upper portion of the face, leaving openings for the eyes, and with straps which could be fastened around the head. The inner chamber of the plastic mask was filled with a blue-colored liquid. The instructions stated that each article could be made into a "Hot Pak" by placing it in warm or hot water for a few minutes and into a "Cold Pak" by placing it in a refrigerator until chilled.

LIBELED: 1-20-58, N. Dist. Ill.

CHARGE: 502(a)—the ctn. labels of the articles, when shipped, contained false and misleading representations that the articles were effective for relieving stiff joints, earache, sore throat, nosebleeds, swellings, and pain due to sinus conditions, and for rejuvenating the skin, reducing puffiness and redness of the skin and overcoming eyestrain.

DISPOSITION: 3-19-58. Default—destruction.

5618. Vitozone ozone generator device. (F.D.C. No. 40958. S. No. 73-821 M.)

QUANTITY: 23 devices at Salt Lake City, Utah.

SHIPPED: Between 7-19-57 and 8-13-57, from Hollywood, Calif., by Vitozone Co.

LABEL IN PART: "Vitozone Ozone Generator."

ACCOMPANYING LABELING: Leaflets designated "Vitozone Proudly Presents Air Conditioning," "Vitozone 'Living Air' Ozonator," "Survey Indicates 70 pct. of Americans Breathe Dirty Air," "Pageant 'Ions' for Health," "Ozone—To Whom It May Concern," and "Science—Of Ions and Men."

RESULTS OF INVESTIGATION: Examination showed that the article consisted of an electrically operated device, with glass discharge tubes capable of forming ozone in the atmosphere.

LIBELED: 11-19-57, Dist. Utah.

CHARGE: 502(a)—when shipped and while held for sale, the labeling accompanying the device contained false and misleading representations that the device was effective in the treatment of asthma, respiratory diseases, other illnesses due to breathing impure air, hay fever, heart disease, high blood pressure, sinusitis, arthritis, rheumatism, cancer, virus invasion, influenza, migraine, and cancerous tumors, and in promoting healing of wounds, calming nerves, and sharpening appetites.

DISPOSITION: 2-28-58. Default—delivered to the Food and Drug Administration.

DRUGS FOR VETERINARY USE

5619. Pratts liquid wormer. (F.D.C. No. 41373. S. No. 40-175 M.)

QUANTITY: 13 4-oz. btls., 3 8-oz. btls., 7 1-qt. btls., and 1 1-gal. btl. at Stockton, Ill.

SHIPPED: 10-7-57, from Junction City, Ky., by Pratt Food Co.

LABEL IN PART: (Btl.) "Pratts Liquid Wormer For Use With Drinking Water * * * Active Ingredients . . . 36.20% Piperazine Hexahydrate Base Inactive Ingredients . . . 63.80% * * * Directions For Pigs: * * * mix 2 ounces (4 tablespoonsfuls) of Pratts Liquid Wormer in 5.0 gallons of drinking water."

LIBELED: 1-24-58, N. Dist. Ill.

CHARGE: 502(a)—the label of the article, when shipped, contained false and misleading representations that the article, when used as directed, was an adequate and effective treatment for the removal of round worms (ascarids) and nodular worms in swine.

DISPOSITION: 2-25-58. Consent—claimed by Pratt Laboratories, Inc., and relabeled.

5620. Worm-Kill. (F.D.C. No. 41394. S. No. 89-873 M.)

QUANTITY: 7 ctns. at Blackfoot, Idaho.

SHIPPED: 8-14-57, from Durango, Colo., by Colorado Livestock & Poultry Remedy Co.

LABEL IN PART: "Worm-Kill The All Purpose Wormer * * * Hogs * * * Sheep * * * Cattle * * * Chickens * * * Contents: KMNO3, Sulfur, Copperas, Nicotine."

ACCOMPANYING LABELING: Leaflets reading, in part, "Worm-Kill * * * Highly Recommended for Prevention of Ticks and Lice on Poultry and Livestock and as a Wormer is Unexcelled."

LIBELED: 2-7-58, Dist. Idaho.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was effective for treating all types of worm infestations in livestock and poultry and preventing infestations by ticks and lice on livestock and poultry.

DISPOSITION: 3-10-58. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 5581 TO 5620

PRODUCTS

[1] (5582) Seizure contested. Contains opinion of the court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5582) Seizure contested. Contains opinion of the court.

U.S. GOVERNMENT PRINTING OFFICE: 1959

D.D.N.J., F.D.C. 5621–5640 Issued October 1959

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5621–5640

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve seizure proceedings in which decrees of condemnation were entered after default or consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *October 20, 1959*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see Nos. 5624, 5631; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 5624, 5631.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5621–5640

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength and quality differed from that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(2), the article was in package form, and it failed to bear a label containing an accurate statement of the quantity of contents; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the quantity, kind, or proportion of alcohol contained therein; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 502(f)(2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods of duration of administration or application, in such manner and form, as are necessary for the protection of users.

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5621. Clarimycin. (F.D.C. No. 41634. S. No. 8–347 P.)

QUANTITY: 880 display cards, each containing 1 btl., at Pittsburgh, Pa.

SHIPPED: 12–9–57, from Jersey City, N.J., by Merritt Corp.

LABEL IN PART: (Btl.) "Contents: 5 Drams Clarimycin Anti-Biotic Acne Lotion * * * Active Ingredients: Neomycin Sulphate, Allantoin."

RESULTS OF INVESTIGATION: The article was regarded as a new drug since it was represented to contain neomycin sulfate and was labeled with directions for use over an extended period of time.

LIBELED: 3–20–58, W. Dist. Pa.

CHARGE: 502(a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for acne, pimples, blackheads, and stubborn skin infections; and 505(a)—the article was a new drug which may not be introduced into interstate commerce, and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: 6–20–58. Default—destruction.

5622. Pega Palo. (F.D.C. No. 41618. S. No. 18–288 P.)

QUANTITY: 142 cellophane pkgs. at Salt Lake City, Utah.

SHIPPED: A portion of the article was transported from Chicago, Ill., in January 1957, by Al Cavey and Dave Farrell, partners in the Pega Palo Sales Co., Salt Lake City, Utah, and a portion of the article was shipped from Chicago, Ill., on 3–1–57, by A–1 Import Co.

LIBELED: 3–14–58, Dist. Utah

CHARGE: 502(f)(1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for its used as an aphrodisiac and as a sex rejuvenator, which were the purposes for which the article was intended; and 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: 8–1–58. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5623. R.D.S. laxative herb. (F.D.C. No. 41495. S. No. 14–969 P.)

QUANTITY: 1,386 pkgs. at Louisville, Ky., in possession of R. D. Smith.

SHIPPED: At various times, from Cincinnati, Ohio.

LABEL IN PART: "Net Contents 1 Oz. * * * R.D.S. Laxative Herbs * * * Active Laxative Ingredients: Senna, Cascara Sagrada. Inactive Ingredients: Saffron, Uva Ursi, Dandelion, Sarsaparilla, Licorice, China Cassia, Anise Seed, Sassafras Bark of Root, Elder Flowers, Cloves and Salicylic Acid * * * Directions: * * * Prepared for R. D. Smith * * * Zanesville, Ohio."

RESULTS OF INVESTIGATION: R. D. Smith was engaged in vending the product to the public, from a sales booth, on the premises of a retail five-and-dime variety store.

LIBELED: 4–10–58, W. Dist. Ky.

CHARGE: 502(f)(1)—the labeling of the article, while held for sale, failed to bear adequate directions for use in overcoming worm infestation, indigestion, sour stomach, rheumatism, and for preventing diseases of all types, which were the purposes for which the salesman, R. D. Smith, orally offered the product.

DISPOSITION: 6–27–58. Default—destruction.

5624. Botanical drugs. (F.D.C. No. 41538. S. Nos. 11–870/81 P, 11–883 P, 11–885/97 P, 11–899/914 P, 11–916/38 P.)

QUANTITY: 1,000 lbs. of various crude botanical drugs in cans, drums, cloth or paper bags, and boxes, and an unknown quantity of botanical drugs repackaged into boxes and into 2-, 6-, 12-, and 32-oz. btls. at Port Huron, Mich., in possession of W. H. McConnell. The crude botanical drugs consisted of such articles as *cascara sagrada, elm, sweetgum,* and *tamarack barks; horsetail* and *knottgrasses; red clover tops; shillingia, blue flag, burdock, yellow dock, poke, berberis, mandrake, sassafras, bayberry, turnip, wild gum,* and *button snakeroots; mullein, buchu, damiana, strawberry, balmony,* and *senna leaves; blue vervian, chickweed; lobelia, scouring rush,* and *boneset herbs;* and *palmetto berries.*

SHIPPED: Between 12–15–48 and 11–18–57, from Jersey City, N.J.

*See also No. 5622.

LABEL IN PART: (Typical specimens on repacked drugs) "No. 11 for Sugar Diabetes Take two tablespoonfuls three times per day," "No. 12 one teaspoonful every three hours," "No. 14 Cancer Liniment Saturate a cloth and apply twice a day," and "No. 45 Kidney Medicine One teaspoonful in a glass of water. Dose, ⅓ morning, noon and night."

ACCOMPANYING LABELING: An unknown quantity of loose, printed and typed labels intended for use on the repacked drugs.

RESULTS OF INVESTIGATION: The repacked drugs had been prepared by W. H. McConnell, by grinding a portion of the crude botanical drugs into a powder and packing into cardboard boxes of 2-oz. and 8-oz. sizes; by grinding to a powder and capsulating the crude drugs, and then packaging the capsules in boxes of 60 or 100 capsules; and by mixing the crude drugs and cooking them with water, and then bottling the liquid extracts into 2-, 6-, 12-, and 32-ozs. btls.

LIBELED: On or about 5–6–58, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, a portion of the labels of the articles contained false and misleading claims for the treatment of cancer, diabetes, sinus infection, "flu," rheumatism, and other serious diseases for which the articles would not be an adequate and effective treatment; 502(b)(2)—none of the labels of the articles bore any statement of the quantity of contents contained therein; 502(e)—the labels of the articles failed to bear (1) the common or usual name of the article, and (2) the common or usual name of each active ingredient contained therein; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, for example, eight of the liquid medicines were intended to be used as "blood purifiers," and their individual labels failed to state the purpose for which they were to be used, and item "No. 12" was intended for use as a "strengthener and growth dissolver," and its label gave no indication for use.

DISPOSITION: 6–10–58. Default—some of the drugs were delivered to the Food and Drug Administration and the remainder was destroyed.

5625. Epsom salt. (F.D.C. No. 41525. S. No. 6–979 P.)

QUANTITY: 210 cases, 12 boxes each, at Providence, R.I.

SHIPPED: 4–9–58, from Boston, Mass., by Atlantic Salt & Chemical Co. (also known as Atlantic Salt Co.).

LABEL IN PART: (Box) "Five Pounds Atlantic Clipper Epsom Salt U.S.P."

LIBELED: 4–21–58, Dist. R.I.

CHARGE: 502(a)—the label of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for biliousness and other digestive disorders; and 502(f)(2)—the article was essentially a laxative, and its labeling failed to bear a warning that frequent or continued use may result in dependence on laxatives to move the bowels.

DISPOSITION: 6–24–58. Consent—claimed by Atlantic Salt Co. and relabeled.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

5626. Posterior pituitary injection. (F.D.C. No. 41625. S. No. 64–360 M.)

QUANTITY: 4 ctns., 100 ampuls each, at Pittsburgh, Pa.

SHIPPED: 11–11–57, from Tuckahoe, N.Y., by Burroughs Wellcome & Co., Inc.

LABEL IN PART: (Ctn. and ampul) "Infundin Posterior Pituitary Injection * * * 1 cc. (10 U.S.P. Units)."

LIBELED: 3–14–58, W. Dist. Pa.

CHARGE: 501(b)—the strength of the article, when shipped, fell below the standard for the article set forth in the United States Pharmacopeia; and 502(a)—the label statement "Posterior Pituitary Injection * * * 1 cc. (10 U.S.P. Units)" was false and misleading as applied to the article, the potency of which was substantially less than 10 U.S.P. posterior pituitary units per cubic centimeter.

DISPOSITION: 6–18–58. Default—destruction.

5627. Pituitary posterior injection. (F.D.C. No. 41612. S. No. 83–304 M.)

QUANTITY: 3 cases, containing a total of 621 vials, at New Castle, Ind.

SHIPPED: 9–10–57 and 9–19–57, from Berkeley, Calif., by Borden Laboratories, Inc.

RESULTS OF INVESTIGATION: Individual vial labels to be affixed by the dealer read in part "10CC Posterior Pituitary Injection * * * 20 U.S.P. Units per CC." Also accompanying the article was a loose label which read in part "Borden Laboratories, Inc. * * * 500 Vials Posterior Pituitary Extract 20 Units U.S.P. ML."

LIBELED: 3–20–58, S. Dist. Ind.

CHARGE: 501(b)—the strength of the article, when shipped, fell below the standard for posterior pituitary extract set forth in the United States Pharmacopeia; and 502(a)—the label statements "Posterior Pituitary Extract 20 Units U.S.P. ML." and "10 CC Posterior Pituitary Injection * * * 20 U.S.P. Units Per CC" were false and misleading as applied to the article, the potency of which was substantially less than 20 U.S.P. posterior pituitary units per milliliter or per cubic centimeter.

DISPOSITION: 6–27–58. Default—destruction.

5628. Amphetidisin-10 capsules. (F.D.C. No. 41577. S. No. 37–724 P.)

QUANTITY: 35 1,000-capsule btls. at St. Louis, Mo.

SHIPPED: 10–17–57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: "1000 Capsules Amphetidisin-10 Timed Disintegration Capsules Dextro-Amphetamine Sulfate 10 Mg. Each Capsule Contains 10 Mg. of Dextro-Amphetamine Sulfate in a Special Base that Provides for Timed Disintegration of the Contents throughout a Period of about 6–10 Hours."

RESULTS OF INVESTIGATION: Analysis showed that the article contained the labeled amount of dextro-amphetamine sulfate of which 88 percent was released within 2 hours.

LIBELED: 2–13–58, E. Dist. Mo.

CHARGE: 501(c)—the quality of the article, when shipped, differed from that which it purported or was represented to possess in that it failed to disintegrate at a uniform rate over a 6- to 10-hour period; and 502(a)—the labeled statement "Timed Disintegration Capsules * * * Each Capsule Contains 10 Mg. of Dextro-Amphetamine Sulfate in a Special Base that Provides for Timed Disintegration of the Contents throughout a Period of about 6–10 Hours" was false and misleading.

DISPOSITION: 3–12–58. Default—destruction.

5629. Rubber prophylactics. (F.D.C. No. 41635. S. No. 27–865 P.)

QUANTITY: 19 gross at Dallas, Tex.

SHIPPED: 10–29–57, from Akron, Ohio, by Killashun Sales Div. of the Akwell Corp.

LABEL IN PART: (Pkg.) "Silver-Tex One Prophylactic."

RESULTS OF INVESTIGATION: Examination of 186 units showed that 1.6 percent were defective in that they contained holes.

LIBELED: 4–2–58, N. Dist. Tex.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported to possess; and 502(a)—the label statement "Prophylactic" was false and misleading as applied to an article containing holes.

DISPOSITION: 5–5–58. Default—destruction.

5630. Trimadine capsules. (F.D.C. No. 41613. S. No. 39–002 P.)

QUANTITY: 15 1,000-capsule btls., 3 500-capsule btls., 19 100-capsule btls., and 9 30-capsule btls. at Oakland, Calif.

SHIPPED: 10–18–57, from Rensselaer, N.Y.

LABEL IN PART: "Trimadine Timed Disintegration Capsules Each Capsule Contains Dextro Amphetamine Sulfate 15 Mg. Thyroid 1½ gr., Atropine Sulfate $\frac{1}{180}$ gr., Acetphenolisatin 0.5 gr., Ascorbic Acid 50 mg., Phenobarbital ¼ gr., * * * each capsule prepared in a special base to allow the disintegration of the contents throughout a 6–10 hour period."

RESULTS OF INVESTIGATION: Analysis showed that the article released more than 72 percent of dextro-amphetamine sulfate within 2 hours.

LIBELED: 3–13–58, N. Dist. Calif.

CHARGE: 501(c)—the quality of the article, while held for sale, differed from that which it purported or was represented to possess in that the article failed to disintegrate at a uniform rate over a 6- to 10-hour period; and 502(a)—the label statement "Timed Disintegration Capsules * * * Each Capsule Prepared in a Special Base to Allow the Disintegration of the Contents Throughout a 6–10 Hour Period" was false and misleading.

DISPOSITION: 5–6–58. Default—destruction.

5631. Romper teething lotion. (F.D.C. No. 41347. S. Nos. 49–013 M, 11–868 P.)

QUANTITY: 1,140 btls. at Detroit, Mich.

SHIPPED: 9–25–56, from Cleveland, Ohio, by H & D Labs, Inc.

LABEL IN PART: (Btl.) "Romper Teething Lotion * * * Contains Benzocaine 3 percent Alcohol 25 percent 15 cc."

RESULTS OF INVESTIGATION: Analysis showed that the article contained benzyl alcohol, and that it contained, also, more than the declared amount of benzocaine and was 23.3 percent short in the volume of contents declared.

LIBELED: 1–9–58, E. Dist. Mich.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it was represented to possess, namely, 3 percent benzocaine per 15 cubic centimeters; 502(b)(2)—the label of the article failed to bear an accurate statement of the quantity of contents; and 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol.

DISPOSITION: 6–23–58. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

5632. Soy lecithin. (F.D.C. No. 41514. S. No. 41-406 P.)

QUANTITY: 1 60-lb. drum and 11 ½-lb. btls. at Parma, Idaho, in possession of Arthur E. Yensen, t/a Yensen Mineral Co.

SHIPPED: 1-9-58, from Portland, Oreg.

LABEL IN PART: (Btl.) "½ Pound (one month's supply) Granular Lecithin * * * One level teaspoonful with each morning and evening meal, or as your doctor directs * * * Distributed by Yensen Mineral Company, Parma, Idaho."

ACCOMPANYING LABELING: Leaflets identified as "Lecithin and Health Compiled from recent literature by: Arthur E. Yensen."

RESULTS OF INVESTIGATION: The article in the btls. was repackaged by the dealer from the above-mentioned bulk drum, and the leaflets were printed locally for use by the dealer in promoting the sale of the article.

LIBELED: 4-16-58, Dist. Idaho.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading respresentations that the article was effective for overcoming hardening of the arteries, anemia, high blood pressure, coronary thrombosis, arthritis, diabetes, liver conditions, prostate troubles, "brain fag," nervousness, emotional irritability, headache, insomnia, and improving the general health of older people.

DISPOSITION: 5-20-58. Default—destruction.

5633. Soy and wheat germ oil concentrate and Energol germ oil concentrate. (F.D.C. No. 41518. S. Nos. 38-891/2 P.)

QUANTITY: 5 8-oz. btls. of *soy and wheat germ oil concentrate*, and 11 16-oz. and 5 32-oz. cans of *Energol germ oil concentrate* at San Francisco, Calif.

SHIPPED: 11-25-57 and 1-30-58, from York, Pa., by York Barbell Co.

LABEL IN PART: (Btl.) "Hoffman's Soy Germ Oil Wheat Germ Oil Concentrate" and (can) "Hoffman's Energol Germ Oil Concentrate."

ACCOMPANYING LABELING: Leaflets entitled "Hoffman's Germ Oil Concentrate" and "Test Taste Compare Hoffman's High Protein Food Products."

LIBELED: 4-21-58, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the need in human nutrition for linoleic acid, choline, inositol, and vitamin E, contained in the articles, was recognized and established; that the use of the articles would insure a hormone balance in the body and build enzymes, would give one health, strength, and endurance; and would be effective in preventing or treating physical or sexual weakness, arteriosclerosis, coronary thrombosis, eczema, Buerger's disease, gallstones cell production, cirrhosis of the liver, gangrene, sore tongues, nervousness, anemia, epilepsy, difficulty in walking, pathological changes in the liver, thyroid and sex glands, inflamation of the intestines, extreme fatigue, oil secretion in eyelashes, bloodshot lip, swelling under eyes, quarrelsomeness, mental sluggishness, numbness, low blood pressure, shortage of breath, severe headaches, gas pains, flatulence, insufficient gastric juices, lack of hydro-

*See also Nos. 5621, 5624-5630.

chloric acid, shingles, arthritis, alcoholism, underactive pituitary glands, waddling gait, unusual sensitivity to pain, changes in the bone marrow, changes in the nodes, lack of fertility, changes in the nerves, stunted growth, middle age spread, premature aging, overweight, stimulation of bile, coronary thrombosis, heart attacks, sore mouths, mental depression, insomnia, dizziness, irritability, tremors, nervous tics, blackouts, cataracts, tongue abnormalities, watery eyes, inefficiency, depression, sensitivity to noise, low basic metabolism, enlarged heart, vomiting, muscular contraction of the stomach, headache, diarrhea, trifacial neuralgia, sciatica, rheumatism, irregular menstruation, lack of strength, skin lesions, emaciation, sexual disturbances, coco pigmentation, changes in the brain cells, lagging secondary sex characteristics, swelling of the feet and ankles, inactive ovaries, muscular and joint stiffness, diabetes, gangreneous ulcers, coronary occlusion, premature old age, sore lips, menstrual irregularities, extreme weakness, nausea, convulsions, paralysis, tension, duodenal ulcers, adrenal deficiency, aching feet, neuritis, bloodshot eyes, early menopause, weak eyes, burning eyes, forgetfulness, constipation, high blood pressure, heart palpitation, pain in muscles, low energy production, sick stomach, heart abnormalities, severe headaches, lumbago, premature aging, premature menopause, lack of co-ordination, eye infection, ear infections, changes in the lymph, changes in the spleen, too rapid growth, edema, muscular distrophy, and strains.

DISPOSITION: 2–27–59. Default—5 btls. of the *soy and wheat germ oil concentrate* and 10 copies, each, of the accompanying leaflets were delivered to the Food and Drug Administration, and the remainder of the articles was destroyed.

5634. Honey with royal jelly and royal jelly capsules. (F.D.C. No. 41504. S. Nos. 3–870/3 P.)

QUANTITY: 18 1-lb. 4-oz. jars of *honey with royal jelly*, and 27 15-capsule btls., and 2 boxes, each containing 1 15-capsule vial of *royal jelly*, at Baltimore, Md., in possession of Special Diet Shop, Inc.

SHIPPED: Between 11–21–57 and 1–23–58, from New York, N.Y.

ACCOMPANYING LABELING: Posters entitled "Reprints of Scientific News Reports on Royal Jelly" and "Royal Jelly Universally Acclaimed."

RESULTS OF INVESTIGATION: The posters were used by the dealer for promotion purposes as part of a window display of the article.

LIBELED: 4–7–58, Dist. Md.

CHARGE: 502(a)—the labeling accompanying the articles, while held for sale, contained false and misleading representations that the articles would aid in the cure of cancer, prevent aging, would be efficacious in many physical ailments useful in treating premature, undernourished, and diseased infants, would successfully treat arthritis, leukemia, and ulcers, and restore vitality.

DISPOSITION: 5–21–58. Default—destruction.

5635. Royal jelly capsules with vitamins and royal jelly cream. (F.D.C. No. 41515. S. Nos. 3–543/6 P.)

QUANTITY: 1 canister containing 175 capsules, 1 canister containing 1,050 capsules, 1 canister containing 1,450 capsules, and 1 150-capsule btl., 10 100-capsule btls., 3 50-capsule btls., and 6 30-capsule btls., of *royal jelly with vitamins*, and 286 jars of *royal jelly cream*, at Washington, D.C., in possession of Tipton & Myers.

SHIPPED: 3–15–58 and 3–17–58, from Brooklyn, N.Y., and Newark, N.J.

LABEL IN PART: (Btl.) "Rex Royal Jelly With Vitamin Capsules * * * Formula per capsule: Royal Jelly 12½ mg. [or "25 mg."] Vitamin B–1 10 mg. 1000% MDR Vitamin B–2 5 mg. 250% MDR Vitamin B–6 1 mg. Vitamin C 50 mg. 166% MDR Vitamin B–12 3 mcg. Folic Acid 0.2 mg. Niacinamide 30 mg. 300% MDR Calcium Pantothenate 2 mg. Suggested Dose: * * * Note: The need for royal jelly in human nutrition has not been fully established. Tipton & Myers * * * Washington 5, D.C." and "Royal Jelly 50 Mg. Alpha Tocopherol 50 I.U. (Vitamin E) Date —— One or More Capsules as Dietary Supplement"; (jar) "Lady Pat Royal Jelly Treatment Creme Cont. 100 mg. Youthifying Queen Bee Royal Jelly to ea. oz. Youthifies–Softens–Smooths * * * Lady Pat Washington, D.C. Distributors Nt. Wt. Two Ozs."

ACCOMPANYING LABELING: Window display and counter cards entitled "Royal Jelly: New Miracle Aid," "Royal Jelly: New Miracle Aid * * * On a Sunny April Morning," "More About Royal Jelly," and "Royal Jelly The Queen Bee's Secret Food of Vitality and Long Life."

RESULTS OF INVESTIGATION: The capsules in the btls. had been shipped in the above-mentioned canisters, as described, and upon receipt by the consignee were repackaged and relabeled. The window display and counter cards were photographs of portions of an article on royal jelly that appeared in the December 1957 and January 1958 issues of Popular Medicine. The window display and counter cards were prepared locally by the consignee.

LIBELED: 4–9–58, Dist. Columbia.

CHARGE: 502(a)—the labeling accompanying the articles, while held for sale, contained false and misleading representations that the articles would produce a sense of well being, give one pep and vitality, increase vigor, regenerate flagging sex drive, reinforce cells in the human body, halt mental depression, act as a tranquilizer, stop stomach upsets, lengthen life, revitalize sex drive, strengthen cells, restore sagging breasts, and cure a wide range of illnesses from neurasthenia to arthritis.

DISPOSITION: 5–23–58. Default—delivered to a public institution for its use, and not for sale.

5636. Honey with royal jelly and royal jelly capsules. (F.D.C. No. 41652. S. Nos. 84–444/5 P.)

QUANTITY: 36 jars of *honey with royal jelly* and 3 btls. of *royal jelly capsules* at Erie, Pa., in possession of Dietetic Food Co.

SHIPPED: The *honey with royal jelly* was shipped on 8–19–57, from Los Angeles, Calif., and the *royal jelly capsules* were shipped on 3–4–58 from Chicago, Ill.

LABEL IN PART: (Jar) "Honey With Royal Jelly * * * Net Wt. 1 Lb. 4 Oz. * * * Contains About 3800 Mgs. of Pure Royal Jelly"; (btl.) "Royal Jelly—60 Mg. 50 Capsules."

ACCOMPANYING LABELING: Leaflet entitled "You Must Read These Facts."

RESULTS OF INVESTIGATION: The above-mentioned leaflets were printed locally.

LIBELED: 4–9–58, W. Dist. Pa.

CHARGE: 502(a)—the labeling accompanying the articles, while held for sale, contained false and misleading representations that each article "rejuvenates failing or worn out glands, producing a feeling of youthfulness," "eliminates chronic tiredness," "produces general state of wellbeing," "permits prolonged

intellectual work without tiring," "normalizes growth of underdeveloped children," "gives fast, effective relief to women suffering critical years," and "stimulates appetite and lengthens lives."

DISPOSITION: 5–5–58. Default—destruction.

5637. Desert bath minerals. (F.D.C. No. 41506. S. No. 39–551 P.)

QUANTITY: 376 ctns. at Sacramento, Calif., in possession of Desert Products Distributing Co.

SHIPPED: 8–6–57, from Sparks, Nev., by Desert Minerals Co.

LABEL IN PART: "Desert Bath Minerals * * * Approximate chemical composition (parts per million): Silica * * * 55.2, Iron * * * Trace, Manganese * * * 0., Calcium * * * 176.1, Magnesium * * * 1.5, Sodium * * * 325.0, Potassium * * * 4.1, Bicarbonate * * * 27.5, Sulphate * * * 360.4, Chloride * * * 287.2, Fluoride * * * 0., Nitrate * * * 0., Alumnia * * * 2.4, Copper * * * Trace. Mined, Packed and Sold by Desert Minerals Company * * * Sparks, Nevada Net Weight 20 Ounces."

ACCOMPANYING LABELING: Booklet entitled "The Discovery of Fabulous Desert Bath Minerals," folder entitled "Good News," letterheads of "Desert Products Distributing Company," and posters reading in part "Arthritis–Rheumatism–Irregularity Nature's Way Thru Desert Bath Minerals."

RESULTS OF INVESTIGATION: The booklet was enclosed in the ctns. containing the article. The folder was printed in Sacramento for the shipper and delivered by the shipper to the dealer, and the letterheads and posters were printed on order of the dealer.

LIBELED: 4–14–58, N. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the ctn. label and the accompanying labeling of the article contained false and misleading representations that the article was "live" organic, medicinal agents of health and beauty beneficial in mineral-hungry conditions, and is an adequate and effective treatment for arthritis, gout, rheumatism, metallic poisoning, many skin diseases, catarrhal conditions, sinus irregularity, backache, kidney trouble, chronic diarrhea, uric acid gravel and calculi, syphilis, and hyperemia of liver.

DISPOSITION: 6–12–58. Default—destruction.

5638. Dynamic vibrator. (F.D.C. No. 41532. S. No. 30–181 P.)

QUANTITY: 24 devices at Newark, N.J., in possession of Renhill Products Co.

SHIPPED: 11–15–57, from Bronx, N.Y., by Dynamic Mfg. Corp.

LABEL IN PART: (Ctn.) "Another Fine Product of Dynamic Manufacturing Corp. New York, N.Y."; (device) "Model M AC–DC 115 Volts 36 Watts."

ACCOMPANYING LABELING: Leaflets entitled "Now You Can Get New Vitality At Home," "Now You Can Slenderize At Home," and "There's New Body Beauty."

RESULTS OF INVESTIGATION: The leaflets entitled "There's New Body Beauty" were prepared and printed at Newark, N.J., on order of the dealer, and the other leaflets were obtained by the dealer from the shipper of the device.

Examination of the device revealed that it was a vibrator powered by a single electric motor fitted with an elongated commutator shaft, eccentrically weighted to cause the motor to vibrate. The motor was contained within a small plywood box which was wrapped with a sponge-like plastic cushioning material covered with Duran plastic.

LIBELED: 5–2–58, Dist. N.J.

CHARGE: 502(a)—the labeling accompanying the article, when shipped and while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for stimulating blood circulation, relaxing nervous tension, increasing body nutrition, improving general metabolism, relieving simple constipation, reducing the figure, decreasing fatigue, relieving aches and pains from arthritis, rheumatism, lumbago, and bursitis, overcoming fibrositis, breaking down excess fatty tissue, overcoming muscular ailments, providing pep, vitality, comfort, and happiness, and being of value as a general body conditioner.

DISPOSITION: 6–10–58. Default—destruction.

5639. Jacuzzi whirlpool bath device. (F.D.C. No. 41574. S. No. 18–428 P.)

QUANTITY: 17 devices, at Denver, Colo.

SHIPPED: Between 8–8–57 and 5–7–58, from Berkeley, Calif., by Jacuzzi Bros., Inc.

ACCOMPANYING LABELING: Brochures entitled "Jacuzzi Whirlpool Bath," "The Whole Family Loves Jacuzzi Whirlpool Bath," and "Jacuzzi Whirlpool Bath * * * For Professional Use Only," and posters designated "Feel Good Again In Your Own Bathtub," "P–G and E Progress," and "The Whole Family Loves the Jacuzzi Whirlpool Bath."

RESULTS OF INVESTIGATION: Examination showed that the device had an enclosed electric motor which would drive a water pump. The water was forcefully driven through a nozzle and air aspirator, thus producing a swirling air-water foam.

LIBELED: 5–28–58, Dist. Colo.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for arthritis, rheumatism, bursitis, and nagging backache, providing passive exercise, beauty treatment, postpolio rehabilitation, and sparkling radiant complexion, preventing accumulation of soft, fatty tissues, varicose veins, and sagging muscles, toning muscles and firming tissues, adding years to one's life and keeping one free of old age miseries, keeping one slim and trim and making the daily bath become a "fountain of youth," washing away worry lines, attaining figure and vital complexion control, improving circulation, and keeping robust and virile.

DISPOSITION: 5–8–59. Consent—claimed by Jacuzzi Brothers, Inc., and relabeled.

DRUG FOR VETERINARY USE

5640. Poultry mixtures and poultry and livestock mixture. (F.D.C. No. 41523. S. Nos. 27–927/30 P.)

QUANTITY: 229 1-gal. jugs, 167 1-qt. btls., and 614 1-pt. btls., of *poultry and livestock mixture*, and 26 1-lb. 6-oz. pkgs. of *poultry mixtures* at New Orleans, La.

SHIPPED: 2–1–58, from Grand Bay, Ala., by Marguerite Newman.

LABEL IN PART: (Containers) "Ladner's Improved Poultry and Livestock Mixture * * * Contents: Magnesium Sulphate, Calcium Hydroxide, Sulphur, Furrous Sulphate, Oil of Turpentine and Nicotine. Inert: 60%" and "Ladner's Improved Poultry Mixtures * * * Contents: Epsom Salts 11.96 per cent Commercial Sulphur 11.11 per cent Slacked Lime 68.00 per cent Iron Hydroxide 7.68 per cent Acid Insoluble Residue 1.95 per cent."

ACCOMPANYING LABELING: Leaflets designated "Ladner's Tonic for Hogs, Cows, Calves, Mules" and a number of loose labels for the articles.

LIBELED: 4–18–58, E. Dist. La.

CHARGE: 502(a)—when shipped, the labels of the articles and the accompanying leaflets contained false and misleading representations that the *poultry and livestock mixture* was an adequate and effective treatment for colds, "Air-sac Disease," worms, coccidiosis, mites, fleas, lice, and other bloodsucking parasites in poultry; for mange, worms, and fleas in dogs; for worms, grubs, bloodsucking insects, flies, and scours in calves and all other livestock; and that the *poultry mixtures* were an adequate and effective treatment for cholera, roup, sorehead, and white diarrhea in poultry, and would insure better egg production.

DISPOSITION: 6–10–58. Default—destruction.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U.S. GOVERNMENT PRINTING OFFICE: 1959

D.D.N.J., F.D.C. 5641–5660 Issued December 1959

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5641–5660

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, when shipped to a holder of a guaranty, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent and (2) a criminal proceeding terminated upon a plea of nolo contendere. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firm and individual* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *November 30, 1959.*

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*For presence of a habit-forming substance without warning statements, see No. 5649; omission of, or unsatisfactory, ingredient statements, No. 5649; failure to bear a label containing an accurate statement of the quantity of the contents, No. 5649; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 5649.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5641–5660

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength and quality differed from that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(l), one article was, or purported to be, or was represented as, a drug composed partly of dihydrostreptomycin, a derivative of streptomycin, and another article was represented as a drug containing bacitracin, and neither of the articles was from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New Drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5641. Vitamin B_{12} injection. (F.D.C. No. 41235. S. No. 75–724 M.)

QUANTITY: 52 vials at Riverside, Calif.

SHIPPED: 11–13–57, from Memphis, Tenn., by Morton Pharmaceuticals.

LABEL IN PART: "10 cc Vial * * * Vitamin B_{12} Crystalline USP 1000 micrograms per cc * * * Intramuscular-Intravenous."

RESULTS OF INVESTIGATION: Examination showed that each cubic centimeter of the article contained 988 micrograms of cyanocobalamin (vitamin B_{12}), 9.05 milligrams of sodium chloride, and a substantial amount of unidentified dissolved material, the presence of which was not stated on the label.

LIBELED: 12–20–57, S. Dist. Calif.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for *cyanocobalamin injection* set forth in the United States Pharmacopeia since it contained a substantial amount of unidentified

dissolved material in addition to those constituents permitted to be present in *cyanocobalamin injection;* 505(a)—the article, because of the presence of unidentified dissolved material, was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective.

DISPOSITION: 3–23–59. Consent—destruction.

5642. Vitamin B_{12} injection. (F.D.C. No. 40316. S. No. 43–464 M.)

QUANTITY: 3 ctns. containing a total of 1,550 10-cc. vials at St. Louis, Mo.

SHIPPED: 5–20–57, from Chicago, Ill., by Hallmark Laboratories, Inc.

LABEL IN PART: (Shipping ctns.) "Vitamin B_{12} 1000 mcg. per cc (Cyanocobalamin, U.S.P.) in water for injection. Sodium chloride 0.9% Benzyl alcohol as bacteriostatic agent, 2% average dose: 1 cc for intramuscular and intravenous use. * * * Hallmark Laboratories, Inc., Chicago, Illinois."

RESULTS OF INVESTIGATION: Examination showed that each cubic centimeter of the article contained 978 micrograms of cyanocobalamin (vitamin B_{12}), 8.32 milligrams of sodium chloride, and a quantity of unidentified dissolved material.

LIBELED: 6–7–57, E. Dist. Mo.; amended libel 6–18–57 and 4–4–58.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for *cyanocobalamin injection* set forth in the United States Pharmacopeia since it contained a quantity of dissolved material which is not permitted by the standard as an ingredient of *cyanocobalamin injection;* and 505(a)—the article, because of the presence of unidentified dissolved material, was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective.

DISPOSITION: Hallmark Laboratories, claimant, filed an answer denying that the article was adulterated or a new drug as charged. The Government filed written interrogatories which claimant answered in part and objected to in part. Subsequently, the Government filed a motion to compel further and more complete answers and also a motion for discovery and production of documents. The claimant took issue with the Government's motions, and after a hearing on 12–16–58, the court ordered the claimant to answer some of the interrogatories and sustained claimant's objections to the remainder. The Government's motion for discovery and production of documents was sustained. Thereafter, on 3–11–59, claimant having consented, a decree of condemnation was entered and the article was destroyed.

5643. Pyrdex. (F.D.C. No. 40882. S. No. 53–628 M.)

QUANTITY: 340 vials at Bellaire, Tex.

SHIPPED: 8–9–57, from Los Angeles, Calif., by E. S. Miller Laboratories, Inc.

LABEL IN PART: "No. 320 Pyrdex 10 CC. Vial Each CC. Contains Pyrilamine Maleate 25 Mg. Dextro-Amphetamine HCL 2 Mg. * * * Control #16071."

LIBELED: On or about 10–28–57, S. Dist. Tex.

CHARGE: 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: 7–31–58. Consent—destruction.

5644. Thorazine hydrochloride tablets, Butazolidin tablets, Ansolysen Tartrate tablets, Serpasil Apresoline tablets, Doriden tablets, Meticortelone tablets, and Meticorten tablets. (F.D.C. No. 39504. S. Nos. 61–941/43 M, 61–946/9 M.)

QUANTITY: 41 50-tablet vials of *Thorazine hydrochloride tablets;* 14 100-tablet vials and 5 1000-tablet vials of *Butazolidin tablets;* 19 100-tablet vials of *Ansolysen Tartrate tablets;* 12 100-tablet vials of *Serpasil Apresoline tablets;* 14 100-tablet btls. of *Doriden tablets;* 37 100-tablet vials of *Meticortelone tablets;* and 19 100-tablet vials of *Meticorten tablets* at Woodside, N.Y., in possession of Henry Schein.

SHIPPED: At various times, including July or August, 1956, from Philadelphia, Pa.; Cleveland, Ohio; Summit, N.J.; and Bloomfield, N.J.

RESULTS OF INVESTIGATION: The articles were all new drugs which had been repackaged by the dealer, Henry Schein, under his own labels.

LIBELED: 10–8–56, E. Dist. N.Y.

CHARGE: 505(a)—the articles were new drugs which may not be lawfully introduced into interstate commerce since applications filed pursuant to law were not effective with respect to such drugs.

DISPOSITION: Henry Schein appeared as claimant and filed an answer to the libel on 11–21–56. The Government served written interrogatories upon the claimant. Subsequently, answers were filed to the interrogatories after which the Government filed a motion for summary judgment. On 2–6–59, the court handed down the following decision in denial of the motion:

RAYFIEL, J., *District Judge:* "The plaintiff moves for summary judgment under Rule 56 of the Federal Rules of Civil Procedure.

"The Government commenced this action by filing a libel in rem for the seizure and condemnation of certain vials and bottles containing various kinds of drugs which had been shipped in interstate commerce by their respective manufacturers to one Henry Schein, the claimant herein, a pharmacist of Woodside, Queens County, New York, in this District, and repacked and relabeled by him.

"The basis for the libel was the claim, made by the Government, that the said claimant had not filed 'New Drug' applications with the Secretary of Health, Education and Welfare for the repacked articles, as required by the Federal Food, Drug and Cosmetic Act, Title 21, U.S. Code, Sections 301 et seq.

"Section 355(a) of said title provides that no person shall introduce a new drug in interstate commerce unless an application, filed pursuant to subsection (b) thereof, is effective with respect thereto. Subsection (b) sets forth the requirements of the application, such as reports of investigations as to the safety thereof, its components, specimens of labels, etc.

"The claimant contends, and the Government does not deny, that the manufacturers of *all* of the drugs seized have filed the applications required by Section 355(a), and that they are effective. The Government argues, however, that because the drugs have been *repacked* by the claimant, and in some instances *relabeled*, he, too, is required to file effective 'New Drug' applications therefor.

"The claimant admits that he did not file such applications, but contends that he was not required to do so, since he did nothing more with the drugs in question than repack them in smaller containers and quantities for sale *only* to physicians and institutions such as hospitals, etc.

"It is apparent, therefore, that there are triable issues presented which can be disposed of only by a trial.

"Accordingly, the motion for summary judgment is denied."

On 3–26–59, with the consent of the claimant and the Government, a decree was entered dismissing the libel against the *Ansolysen Tartrate, Serpasil Apresoline, Doriden, Meticortelone,* and *Meticorten tablets,* and ordering that

such articles be returned to the claimant. In addition, on the same day, a consent decree of condemnation and destruction was entered against the *Thorazine hydrochloride tablets* and the *Butazolidin tablets.*

5645. Beauty for Life Capsules. (F.D.C. No. 41312. S. Nos. 24–644 M, 75–231 M.)

QUANTITY: 205 75-capsule btls. at El Segundo, Calif.

SHIPPED: 10–16–57, from Roslyn, N.Y., by Helena Rubenstein, Inc.

LABEL IN PART: "Beauty For Life Three Capsules Contain * * * Vitamin A 4000 U.S.P. Units Vitamin D 400 U.S.P. Units Vitamin B_1 * * * 1 mg. Vitamin C * * * 30 mg. Riboflavin * * * 2 mg. Niacin 10 mg. Vitamin B_6 * * * 3 mg. Vitamin B_{12} 9 micrograms Folic Acid 0.6 mg. Calcium Pantothenate 6.6 mg. Gelatin 1800 mg. Royal Jelly 30 mg. * * * Recommended Dosage: Three (3) a day."

LIBELED: 1–6–58, S. Dist. Calif.

CHARGE: 502(a)—when shipped, the name "Beauty For Life Capsules" and the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for restoring abnormal skin, hair, and nails to normal, that it would aid looks and physical well-being, make one look younger, prevent dryness, brittleness, and splitting of nails indefinitely, and would have beneficial effects in treating nervous tension; and 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the drug.

DISPOSITION: 2–7–58. Default—destruction.

5646. Royal jelly capsules. (F.D.C. No. 40974. S. No. 55–060 M.)

QUANTITY: 585 capsules in btls. at Louisville, Ky., in possession of Royal Drugs of Kentucky.

SHIPPED: 10–11–57, from Cambridge, Mass.

LABEL IN PART: "15 Capsules Queen Bee Brand Royal Jelly * * * Distributed by Royal Drugs of Ky. * * * Each capsule contains 50 mg. Royal Jelly * * * Dietary Supplement."

ACCOMPANYING LABELING: Reprints entitled "Royal Jelly, by R. B. Willson."

RESULTS OF INVESTIGATION: The capsules in the bottles were repackaged and relabeled by the consignee from bulk stock which had been shipped as described above. The above-mentioned accompanying labeling had been produced locally from a reprint of an article in the "American Bee Journal."

LIBELED: 12–4–57, W. Dist. Ky.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that *royal jelly* would prolong life, produce sexual rejuvenation, cure cerebral neuritis (pains in the head and down the arm), arthritis, diabetes, asthma, failing eyesight, sterility in women, impotency in men, and increase lactation in women; and 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: 3–14–58. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUGS FOR VETERINARY USE

5647. Para-Strep Dust. (F.D.C. No. 41571. S. No. 33–893 P.)

QUANTITY: 15 cases, each containing a total of 175 btls., at Frankford, Del.

SHIPPED: 4–2–58, from W. Caldwell, N.J., by Rockland Chemical Co., Inc.

LABEL IN PART: (Btl.) "Rockland PARA-STREP Dust * * * An Aid in the Treatment of * * * Chronic Respiratory Disease or Air Sac Infection in Chickens * * * Contents equivalent to 25 Grams Dihydrostreptomycin Base and 50 Grams Para-Amino-Benzoic Acid * * * Contents sufficient to treat 1000 chickens."

LIBELED: 5–22–58, Dist. Del.

CHARGE: 502(l)—when shipped, the article purported to be and was represented as a drug composed in part of dihydrostreptomycin, a derivative of streptomycin, and it was not from a batch with respect to which a certificate or release had been issued in accordance with regulations.

DISPOSITION: 10–30–58. Default—destruction.

5648. Bacitracin ointment (veterinary). (F.D.C. No. 41353. S. No. 78–036 M.)

QUANTITY: 335 boxes, each containing 1 syringe, at Lincoln, Nebr.

SHIPPED: 2–21–57, from Inglewood, Calif., by Delta Laboratories.

LABEL IN PART: "Mitox Active Ingredients Per Syringe Bacitracin 3200 Units * * * Veterinarians only * * * Control No. 2175 Expiration Date: Feb. '59."

RESULTS OF INVESTIGATION: Examination showed that the article contained substantially less bacitracin than the label declared.

LIBELED: 1–21–58, Dist. Nebr.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 3200 units per syringe; 502(a)—the label statement "Per Syringe Bacitracin 3200 Units" was false and misleading; and 502(l)—the article contained bacitracin, and it was not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: 2–7–58. Consent—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5649. Various drugs. (F.D.C. No. 41501. S. Nos. 38–913/20 P, 38–922/4 P.)

QUANTITY: 76,000 *antacid tablets* in btls., 14 1,000-tablet btls. of *salicylamide tablets*, 9 ctns., 12 50-tablet btls. each, of *vaginal tablets*, 22 btls. of *Cholathol capsules*, 44 btls. of *Entrin tablets*, 12 1,000-tablet btls., and 68 100-tablet btls. of *Satinol tablets*, 83 50-tablet btls. of *diethylstilbestrol tablets*, 14 100-capsule btls. of *Quad capsules*, 52 100-tablet btls. of *thyroid tablets*, 18 1,000-capsule btls., and 1 500-capsule btl. of *amobarbital sodium capsules*, at San Francisco, Calif., in possession of Mark Kaplanoff.

SHIPPED: The *antacid tablets*, *salicylamide tablets*, *Satinol tablets*, *Quad capsules*, and *amobarbital sodium capsules* were shipped from Rensselaer, N.Y., by the Delmar Pharmacal Corp., between 6–25–56 and 1–2–58; the *vaginal tablets* were shipped from Portland, Oreg., by Haack Laboratories, Inc., on 6–28–57; and the *Cholathol capsules*, *Entrin tablets*, *diethylstilbestrol tablets*,

and *thyroid tablets* were shipped from Long Island City, N.Y., by Nysco Laboratories, Inc., between 2–19–57 and 12–30–57.

RESULTS OF INVESTIGATION: The *Cholathol capsules*, *Entrin tablets*, a portion of the *Satinol tablets*, *diethylstilbestrol tablets*, *thyroid tablets*, and a portion of the *amobarbital sodium capsules* were repacked after having been shipped in interstate commerce.

LIBELED: 4–10–58, N. Dist. Calif.

CHARGE: *Antacid tablets.* 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use.

Salicylamide tablets. 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use; and 502(f)(2)—the labeling of the article failed to bear adequate warning against misuse by children since its labeling did not bear a statement that the article should be kept out of reach of children.

Vaginal tablets. 502(b)—when shipped, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Cholathol capsules and *Entrin tablets.* 502(b)—the articles, while held for sale, failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(2)—the labels of the articles failed to bear the common or usual name of each active ingredient; 502(f)(1)—the labels of the articles failed to bear adequate directions for use; and 502(f)(2)—the labeling of the *Entrin tablets* failed to bear adequate warning against misuse by children since its label did not bear a statement that the article should be kept out of reach of children.

Satinol tablets (12-btl. lot). 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use; and 502(f)(2)—the article was essentially a laxative, and its labeling failed to bear a warning against use when nausea, vomiting, (stomach sickness), abdominal pain, (stomach ache, cramp, colic), or other symptoms of appendicitis were present, and its labeling also failed to warn that frequent or continued use may result in a dependence upon laxatives to move the bowels.

Satinol tablets (68-btl. lot). 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 502(f)(2)—the article was essentially a laxative, and its labeling failed to bear a warning against use when nausea, vomiting, (stomach sickness), abdominal pain, (stomach ache, cramp, colic), or other symptoms of appendicitis were present, and its labeling also failed to warn that frequent or continued use may result in a dependence upon laxatives to move the bowels.

Diethylstilbestrol tablets. 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer,

packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(f)(1)—the label of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Quad capsules. 502(b)(1)—when shipped, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(d)—the article contained a quantity of amobarbital, a habit forming derivative of barbituric acid, and its label failed to bear in juxtaposition with the statement of the quantity of such derivative in the article the statement "Warning—may be habit forming"; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Thyroid tablets. 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(1)—the label of the article failed to bear the common or usual name of the article; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its labeling failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Amobarbital sodium capsules (3-btl. lot). 502(d)—when shipped, the article contained a quantity of amobarbital, a habit forming derivative of barbituric acid, and its label failed to bear in juxtaposition with the statement of the quantity of such derivative in the article the statement "Warning—may be habit forming"; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Amobarbital sodium capsules (15-btl., and 1 btl. lots). 502(b)(1)—while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(d)—when shipped, the article contained a quantity of amobarbital, a habit forming derivative of barbituric acid, and its label failed to bear in juxtaposition with the statement of the quantity of such derivative in the article the statement "Warning–may be habit forming"; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The libel alleged also that a number of vitamin and mineral tablets were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1–16–59. Default—the vitamin and mineral capsules were delivered to a charitable institution for its use and not for sale, and the other articles were destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5650. Douche powder. (F.D.C. No. 41427. S. No. 41–182 P.)

QUANTITY: 94 5-oz. jars and 34 12-oz. jars at Seattle, Wash.

*See also No. 5649.

SHIPPED: 1–20–58, from Los Angeles, Calif., by Takara Laboratories Corp.

LABEL IN PART: "Takara Douche Powder * * * Alum, Oil Peppermint, Boric Acid, Phenol * * * For a Douche: Dissolve one teaspoonful of Takara to each quart of comfortably warm water. Use as desired."

LIBELED: 2–14–58, W. Dist. Wash.

CHARGE: 502(f)(2)—the labeling of the article, when shipped, failed to bear such adequate warnings against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users, since its labeling failed to warn that the article should not be used more than twice weekly, unless otherwise directed by a physician.

DISPOSITION: 7–9–58. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

5651. Pentosol. (F.D.C. No. 40611. S. Nos. 25–669 M, 66–340 M, 74–129 M.)

INFORMATION FILED: 3–24–58, N. Dist. Calif., against Invenex Pharmaceuticals, a corporation, San Francisco, Calif., and Jack R. Baker, president.

ALLEGED VIOLATION: On 6–10–57, the defendants gave to a firm engaged in the business of shipping drugs in interstate commerce, including *Pentosol* supplied by the defendants, an invoice containing a guaranty that the *Pentosol* listed in the invoice was neither adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On 6–10–57, the defendants sold, invoiced, and delivered, a quantity of *Pentosol* to the holder of the guaranty at Oakland, Calif.

LABEL IN PART: (Vial) "Pentosol 100cc Multiple Dose Vial Sterile Solution Each cc Contains: Pentobarbital Sodium 1 gr Benzyl Alcohol 2% Water for Injection qs."

CHARGE: 501(c)—the strength of the article differed from that which it purported and was represented to possess, namely, 1 grain of pentobarbital sodium in each cubic centimeter; and 502(a)—the label statement "Each cc Contains: Pentobarbital Sodium 1 gr." was false and misleading since each cubic centimeter of the article contained less than 1 gr. of pentobarbital sodium.

PLEA: Nolo contendere.

DISPOSITION: 8–12–58. Corporation—fined $200; individual—fined $50.

5652. Sodium nitrite and phenobarbital tablets. (F.D.C. No. 41435. S. No. 14–761 P.)

QUANTITY: 3 500-tablet pkgs., 8 100-tablet pkgs., and 21 2,500-tablet pkgs., at Muncie, Ind.

SHIPPED: 10–18–57, from Cincinnati, Ohio.

RESULTS OF INVESTIGATION: Examination showed the article to be a green-colored tablet containing about 0.23 grain of phenobarbital per tablet, or approximately the declared amount, and about 1.38 grains of sodium nitrite per tablet, or about 69 percent of the declared amount.

The article had been repackaged by the consignee from bulk stock shipped as described above.

LIBELED: 3–6–58, S. Dist. Ind.

*See also Nos. 5641, 5642.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it was represented to possess, namely, 2 grains of sodium nitrite per tablet; and 502(a)—the label statement "Each tablet contains Sodium Nitrite 2 gr." was false and misleading.

DISPOSITION: 6–30–58. Default—destruction.

5653. Beta Foplex capsules. (F.D.C. No. 41423. S. No. 90–286 M.)

QUANTITY: 1 drum containing 13,850 capsules, and 15 ctns., each containing 12 btls. of 42 capsules each, at Stamford, Conn.

SHIPPED: 3–30–56, from Long Island City, N.Y.

RESULTS OF INVESTIGATION: The capsules in the bottles were repackaged from the bulk drum by the consignee.

LIBELED: 2–24–58, Dist. Conn.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, 1 milligram of thiamine hydrochloride (vitamin B_1) per capsule; and 502(a)—the label statement "Each capsule contains: * * * Thiamine Hydrochloride * * * 1 mg." was false and misleading as applied to a product which contained less than the declared amount of vitamin B_1 per capsule.

DISPOSITION: 7–12–58. Default—delivered for the use of charitable organizations.

5654. Rubber prophylactics. (F.D.C. No. 41615. S. No. 25–010 P.)

QUANTITY: 248 ctns., each containing ½ gross, at Minneapolis, Minn.

SHIPPED: 9–12–57 and 12–31–57, from Akron, Ohio, by the Killashun Sales Div. of the Akwell Corp.

LABEL IN PART: (Pkg.) "One Sultan Lubricated Prophylactic."

RESULTS OF INVESTIGATION: Examination of 166 *prophylactics* showed that 1.9 percent were defective in that they contained holes.

LIBELED: 3–11–58, Dist. Minn.

CHARGE: 501(c)—the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: 5–21–58. Default—destruction.

5655. Rubber prophylactics. (F.D.C. No. 41479. S. No. 14–370 P.)

QUANTITY: 516 gross at Chicago, Ill.

SHIPPED: 12–20–57, from Akron, Ohio, by Killashun Sales Div. of the Akwell Corp.

LABEL IN PART: "Cello's Prophylactics Latex."

RESULTS OF INVESTIGATION: Examination of 212 *prophylactics* showed three to be defective in that two contained holes and one was excessively fragile.

LIBELED: 3–20–58, N. Dist. Ill.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported to possess; and 502(a)—the label statement "Prophylactics" was false and misleading as applied to an article that was excessively fragile and contained holes.

DISPOSITION: 5–28–58. Default—destruction.

5656. Rubber prophylactics. (F.D.C. No. 41480. S. Nos. 30–107 P, 30–112 P.)

QUANTITY: 238 gross and 748 gross at New York, N.Y.

SHIPPED: 9–26–57 and 1–6–58, from Akron, Ohio, by Akwell Corp.

LABEL IN PART: "Silver Tex * * * Prophylactics" and "Coronet Prophylactics."

RESULTS OF INVESTIGATION: Examination of 288 *prophylactics* from the 238 gross lot showed that 1.4 percent were defective in that they contained holes, and examination of 288 *prophylactics* from the 748 gross lot showed that 1 percent were defective in that they contained holes and were excessively fragile.

LIBELED: 4–14–58, S. Dist. N.Y.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it purported to possess; and 502(a)—the label statement "Prophylactics" was false and misleading as applied to an article that contained holes and was excessively fragile.

DISPOSITION: 5–28–58. Default—destruction.

DRUG FOR VETERINARY USE*

5657. Posterior pituitary injection (veterinary). (F.D.C. No. 40596. S. No. 55–956 M.)

QUANTITY: 2,452 vials at New Castle, Ind.

SHIPPED: 6–7–57, from San Francisco, Calif., by the Borden Laboratory Div. of International Factors.

LIBELED: 8–29–57, S. Dist. Ind.

CHARGE: 501(b)—when shipped, the strength of the article differed from the standard for *posterior pituitary injection* set forth in the United States Pharmacopeia and such difference in strength was not plainly stated on its label; and 502(a)—the label statement "Posterior Pituitary Injection 20 U.S.P. Units Per CC" was false and misleading as applied to the article which had a potency of not more than 13.8 U.S.P. posterior pituitary units per cubic centimeter.

DISPOSITION: 6–27–58. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS†

5658. Ear drops. (F.D.C. No. 41614. S. No. 20–575 P.)

QUANTITY: 225 btls. at Kansas City, Mo.

SHIPPED: 5–29–57, from Omaha, Nebr., by Arman Drug Co., Inc.

LABEL IN PART: "Contents 15 CC. * * * Arman's Ear Drops * * * Benzalkonium Chloride 1:1000 Chlorobutanol * * * 1% * * * Bensocaine and Urea In A Propylene And Glycerine Base."

LIBELED: On or about 3–11–58, W. Dist. Mo.

CHARGE: 502(a)—the label of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for ear infections and earache.

DISPOSITION: 9–11–58. Consent—destruction.

5659. Slim Trim Vibra Pillow. (F.D.C. No. 41566. S. No. 2–511 P.)

QUANTITY: 126 devices at Tampa, Fla.

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*See also No. 5648.
†See also Nos. 5645, 5646, 5648, 5651–5657.

SHIPPED: 4–7–58, from Newark, N.J., by Renhill Products Co.

ACCOMPANYING LABELING: Brochures entitled "There's New Body Beauty" and cards reading in part "Slim Trim Vibra Pillow 1 Year Guarantee."

RESULTS OF INVESTIGATION: Examination of the device showed it to be an electromagnetic type vibrator mounted between two aluminum plates. These plates and vibrator were enclosed by polyurethane foam and a terry cloth cover.

LIBELED: 5–19–58, S. Dist. Fla.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the device was effective for stimulating blood circulation; relaxing nervous tension; increasing body nutrition; improving general metabolism; relieving constipation; reducing the figure; decreasing fatigue; relieving aches and pains from arthritis, rheumatism, lumbago, fibrositis, and bursitis; breaking down excess fatty tissues; aiding nature's own method of overcoming or relieving diseased conditions; providing passive exercise; and promoting and maintaining a general feeling of well being.

DISPOSITION: 7–3–58. Default—destruction.

5660. Electric massage pillow. (F.D.C. No. 41648. S. No. 25–513 P.)

QUANTITY: 63 devices at St. Paul, Minn.

SHIPPED: 2–27–58, from Whitman, Mass., by Morris Struhl Co.

LABEL IN PART: (Ctn.) "Chic Electric Massage Pillow."

ACCOMPANYING LABELING: (Brochure in ctn.) "How To Enjoy * * * Chic Electric Massage Pillow."

LIBELED: 4–2–58, Dist. Minn.

CHARGE: 502(a)—the labeling of the device, when shipped, contained false and misleading representations that the device was capable of providing deep tone massage, helping to melt away fatty tissues, aiding in weight reduction, easing nervous tension, and soothing away aches and pains.

DISPOSITION: 7–8–58. Consent—claimed by Morris Struhl, Inc., New York, N.Y., and relabeled.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 5641 TO 5660

PRODUCTS

[1](5644) Seizure contested. Contains opinion of the court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5644) Seizure contested. Contains opinion of the court.
[2] (5642) Seizure contested.

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